ADMINISTERED PRICES

HEARINGS

BEFORE THE

SUBCOMMITTEE ON ANTITRUST AND MONOPOLY

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

EIGHTY-SIXTH CONGRESS

SECOND SESSION

PURSUANT TO

S. Res. 238

FEBRUARY 23, 24, AND APRIL 20, 1960

PART 19

Administered Prices in the Drug Industry
(General: Pharmaceutical Manufacturers Association)

Printed for the use of the Committee on the Judiciary

UNITED STATES
GOVERNMENT PRINTING OFFICE
35621 WASHINGTON : 1960

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington 25, D.C. - Price $1.00

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ADMINISTERED PRICES

TUESDAY, FEBRUARY 23, 1960

U.S. SENATE,
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to recess, at 9:30 a.m., in the caucus room, Old Senate Office Building, Senator Estes Kefauver, presiding.

Present: Senators Kefauver (chairman), Dirksen, and Hruska.

Also present: Paul Rand Dixon, counsel and staff director; Horace L. Flurry, counsel; Peter N. Chumbris, counsel for the minority; Nicholas N. Kittrie, counsel for the minority; Lucile B. Wendt, attorney; Bushrod Howard, attorney; Dorothy D. Goodwin, attorney; Dr. John M. Blair, chief economist; Dr. Irene Till, economist; Herschel Clesner, special consultant; Paul S. Green, editorial director; and Gladys E. Montier, clerk.

(At the convening of the session, the following are present: Senators Kefauver and Hruska.)

Senator KEFAUVER. The committee will come to order.

Today's witness is Dr. Austin Smith, the president of the Pharmaceutical Manufacturers Association, whose principal office is in Washington. With Dr. Smith are Mr. John K. Worley of Detroit, the general counsel of PMA, and Dr. George F. Lull, M.D. There are also Dr. R. B. Robins, Dr. Arthur DeGraff, Dr. William Apple, Dr. Linwood F. Tice, Dr. Grover C. Bowles, Dr. George L. Scharringhausen, Jr., and Dr. Frederick L. Thomsen. All of them are here to answer questions or if called upon to make statements, are prepared to do so. The biographical sketches of these gentlemen are attached and they will be included in the record.

(The sketches referred to may be found on page 10993.)

Senator KEFAUVER. Before we start I want to welcome Senator Hruska who has been assigned as a member of this committee. Senator Hruska has served with distinction for a number of years as a member of the Senate from Nebraska and as a member of the Judiciary Committee. I am glad that he has been given an assignment on this committee and I know that his contribution will be very substantial. We can assure you, Senator Hruska, there will be plenty of hours in which to make that contribution.

Senator HRUSKA. I am sure that is true, Mr. Chairman, from the observations that I have made personally and what I have been told personally about your efforts on this committee.

Senator KEFAUVER. Dr. Smith and gentlemen, we scheduled these hearings for this week and originally contemplated and made tenta-

tive arrangements to have some other witnesses other than the one set for each day. I had hoped that we would be able to start early and go through until about 12:30 and then recess, come back in the afternoon at 2:15 or 2 o'clock, and carry on until we had finished. But we have a civil rights debate continuing on the Senate floor. I don't know that it will reach a critical point this week or that there will be many votes, but it is important business.

As chairman of this subcommittee, I have been given notice by Senator Dirksen who is the minority leader and also the ranking minority member of this subcommittee. He is interested in this hearing and wants to be present but also wants to be present on the floor of the Senate when the Senate meets and he can't be at two places at the same time. He is entirely within his rights, of course, and he will therefore object to our sitting when the Senate is in session. That is our situation. We will have the same problem with a different group of witnesses tomorrow and the next day and the following day probably. I know of no other way of doing this, since obviously we can't ask you gentlemen to stay here indefinitely, except to go on as far as we can in the morning and then if necessary to recess over until 30 minutes after the Senate adjourns and continue on at that time at night.

I know this will work an inconvenience on witnesses and the press and members of the committee and the staff and everybody else and it is not a very satisfactory way. But this is a very important hearing. We have other sets of hearings that must be held. I am anxious to get legislative recommendations and see if we can get them before the appropriate committees with the testimony that has been presented so that the bills can be facilitated. Then we must get on with other hearings that the committee has planned on other subjects.

That is our situation.

Senator Dirksen has just come in. I was just saying, Senator Dirksen—after I had first welcomed Senator Hruska as a new member of this committee—that as chairman I have been given notice that you would object to our sitting when the Senate is in session.

(At this point, Senator Dirksen entered the hearing room.)

I knew of nothing else to do except to carry on as well as we can in the morning, and then recess until 30 minutes after the Senate adjourns. Any witness who isn't through will have to finish up then.

Senator DIRKSEN. Mr. Chairman, I have an idea we will run late tonight and we will probably run late every night this week. Next week will run late I am sure. I doubt very much if the members of the committee after a long day would have a great disposition to come to take testimony at 9 o'clock at night. I think I would rather rebel at the idea, and I must express my regret. I would have to interpose an objection to the subcommittee meeting when the Senate is in session.

As you know, I have an abiding interest in these hearings and the subject matter, but I find it impossible to pursue my duties as minority leader when the Senate is in session and be here at the same time.

This is not an arbitrary attitude on my part, I can assure you, but it is only in pursuit of what I think is my responsibility to this committee, and as you well know I have been a member of this subcommittee a long time, that I had to take a position. I know, of course,

it will develop some inconvenience for witnesses, and I know also that it disturbs your timetable and your earnest hope and desire to have this matter concluded as quickly as possible.

But that is my difficulty, and I utter it as you well know in the utmost of good faith.

Senator KEFAUVER. That is certainly your right, as I have explained. But unless we can have some night hearings, I don't know when we will ever get through. I suppose all during this session we are going to be very busy on matters before the floor. It is not unorthodox to have night sessions. This committee has had night sessions before during our investigatons. So unless the witnesses can finish up in the time we have, or unless there is some change in the Senate's plan to sit during the day, I see no alternative but to try to have night sessions.

Senator HRUSKA. Mr. Chairman, it is my understanding that we have a meeting of the entire Judciary Committee at 10:30 and I assume the chairman will abide by the committee rule that when the hour arrives, we will rise so that we may all attend the meeting of the entire committee.

Senator KEFAUVER. That meeting, of course, was supposed to be on Monday. Monday was Washington's Birthday, and it has therefore been postponed to this morning. I would think just as soon as they call us, and other Senators have assembled, we will recess then. Will that be all right?

Senator HRUSKA. Except I presume that the three members of the subcommittee will almost be necessary to make a quorum over there.

Senator KEFAUVER. Suppose we leave it that we will keep in close touch with Senator Eastland and when two or three Senators have assembled then we will recess and go over. But in any event, in order to get anything done this morning, we had better get started.

Dr. Smith, we are glad to have you here.

Let me say that we have part I and part II of your prepared statement, as well as a report by Mr. Woodward and Mr. Adams and a second report entitled "Competition and Profits in the Ethical Drug Industry," by Dr. Thomsen. These will be made a part of the record, in that order.

Was it your deisre that the report by Mr. Woodward and Mr. Adams be made a part of the record also?

Dr. SMITH. Yes, sir.

Senator KEFAUVER. Following your statement, then, that well be done, and the statement by Dr. Frederick L. Thomsen will also be made a part of the record.

Dr. SMITH. Yes, Mr. Chairman.

Senator KEFAUVER. That will follow the statement of Messrs. Woodward and Adams. Are there any other reports or statements which you have here so that all of them can be put in the record at the same time?

Dr. SMITH. There are no other statements.

Senator KEFAUVER. These will all be printed in full, Dr. Smith, so you handle the matter in any way that you wish. In other words, your statement, and the charts and tables and such other information and statistics contained in it will be printed together with your statement, in full.

STATEMENT OF DR. AUSTIN SMITH, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY JOHN K. WORLEY, GENERAL COUNSEL, AND FREDERICK L. THOMSEN, PH. D., ECONOMIC CONSULTANT, PMA; ALSO DR. WILLIAM S. APPLE, SECRETARY AND GENERAL MANAGER, AMERICAN PHARMACEUTICAL ASSOCIATION; GROVER C. BOWLES, DIRECTOR OF PHARMACY SERVICE, BAPTIST MEMORIAL HOSPITAL, MEMPHIS, TENN.; ARTHUR CHRISTIAN DE GRAFF, M.D., PROFESSOR OF THERAPEUTICS, NEW YORK UNIVERSITY, AND CHAIRMAN, SUBCOMMITTEE ON SCOPE, U.S. PHARMACOPEIA; GEORGE FAIRLESS LULL, M.D., ACTING SECRETARY, ILLINOIS STATE MEDICAL SOCIETY; DR. RUFUS B. ROBINS, SURGEON, CAMDEN, ARK., AND MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; GEORGE L. SCHARRINGHAUSEN, JR., PHARMACIST, PARK RIDGE, ILL.; AND DR. LINWOOD F. TICE, DEAN, PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE, PHILADELPHIA, PA.

Dr. SMITH. Thank you. Mr. Chairman and members of the subcommittee, my name is Austin Smith and I am here as president of the Pharmaceutical Manufacturers Association. On behalf of the association I'd like to express appreciation for your willingness to permit me to appear before this subcommittee. As you will recall, last fall I asked for the privilege of being heard to offer some general views on the industry, with the thought that perhaps these views, if they were sufficiently general and explanatory, would be helpful to this subcommittee as it held its deliberations in the months to come.

So I appreciate personally your permission to appear and on behalf of the PMA express the association's appreciation, too.

Senator KEFAUVER. We are very glad to have you, Dr. Smith.

Dr. SMITH. Thank you, Mr. Chairman.

Senator DIRKSEN. Dr. Smith, at this point, you are accompanied by others, aren't you?

Dr. SMITH. Yes.

Mr. Chairman and members of the subcommittee, to conserve your time and to be helpful, I would like not to read the report. Of course, it is too long for reading, or to even read much of it. I would, however, like to speak to some parts of it, and it is my hope that some of the things which would be stressed and the questioning, if there is opportunity for that; which would bring out additional information, will help tell the story of the drug industry, of drugs and most importantly, their relationship to the medical care picture as it exists in the United States, and not unimportantly, as it exists in relationship to medical care elsewhere in the world because of the leadership provided by the United States and by its industries, including the drug industry.

Some time ago, Mr. Dixon kindly called my office to inform me that I could appear before your subcommittee on February 23, and I appreciated Mr. Dixon's call, but I was without voice then. Unfor-

tunately the pharmaceutical industry had not yet found a treatment for laryngitis.

Senator DIRKSEN. If you find it let me know, will you?

Dr. SMITH. I will. So I could only convey the information to Mr. Dixon by written note to other individuals, and I hope that this was helpful and not inconvenient.

However, at that time there was another evidence of illness which with my medical background and instincts I must admit concerned me a little, and so I was a little worried about that and took some drugs. Now I mention this by way of setting the stage, if I can describe it that way, for the discussion and the views which will follow.

I should have known better as a physician not to try to push myself because a patient would be advised otherwise. But subsequently I did take antibiotics, and I felt effectively, because unquestionably there was pneumonia imminent, and presumably that danger has now passed. But the significant thing I believe was the fact that I was reminded to do something for myself that I would have thought unhesitatingly to do for a patient, by advertising material which crossed my desk, a little black and white folder which reminded me of this particular antibiotic, and reminded me of its significance.

Therefore, today I guess I speak with some conviction about the value of drugs and the value of advertising, and these are points which have been discussed by the committee and to which I will refer a few moments later in the presentation.

To do this may I ask this question, Senator?

I wonder if any member of the subcommittee knows how much it costs to die? According to the information that is available, death costs about $900, and that does not include legal fees or doctor's fees, only the funeral director and the embalming service and the coffins and the monuments and the tombstones and the cemetery services.

The antibiotic that I took, I prescribed for myself—4 capsules daily for 8 days—at a list price of $15.30. I thought this was quite an investment for me, and I suppose that this is one time when I could feel that the price of drugs is low. In fact for years I have been speaking of the low cost of drugs. And now for the presentation itself.

There are charts to accompany the typewritten presentation or the mimeographed presentation which you have.

I believe though, Mr. Senator, that perhaps I could lend some emphasis to some of the points that I would like to make if I could place before you two bags. These are doctor's bags. The one on the left is a bag that is outfitted as a doctor 25 years ago would carry it.

The one on the right is outfitted with the drugs that are used today. This is most significant because in this bag of 25 years ago there is not one drug that is life saving. They are all palliative, and in here you will find things ranging from castor oil to the old fashioned remedies that we might rub on our throats or our chests.

And in this other bag you will find tablets and injectable preparations which are not only effective in reducing suffering and lessening the cost of dying, but these also are economic aids as they put people back to work more quickly and lessen the drain on the community and on the family budget.

With these as examples of a change in times in just 25 years, my presentation will be confined to just about that period, because this has been the birth of modern chemotherapy or drug therapy.*

I would like during my presentation to give a reasonably complete picture of the operations of this industry in capsule form, since time is working against all of us. I have been concerned and I am concerned now that there is a great danger of the public misunderstanding if attention is focused on a single product or on a single company, because after all, there are few companies which make only a single product.

This is an industry represented by many companies and most companies make many products. So I would like to emphasize as a general observation my hope that not a single company or a single product would be used as an example of the present status of the drug industry, but that we can discuss the drug industry as a whole, and in fact that is all that I can do. As an officer of the Pharmaceutical Manufacturers Association, I cannot speak to the activities of a single pharmacy or to the pricing structure of, or anything else about, a single product.

I will, however, not ignore the purpose of the inquiry and that is prices as a whole and the activities of the industry as a whole.

I hope also to be able in my testimony to demonstrate that the competitive pharmaceutical industry in the United States has played a role without parallel anywhere else in the world, and I would like to point out, and I hope to prove, that these revolutionary advances of recent years in the drug field have been the direct result of the competitive forces at work within this industry.

Since 1947 this industry has spent about $1 billion in research alone, and on your left, gentlemen, is a chart which will show the gamble that is taken with the research efforts of this industry.

Information that is available on survey by the Pharmaceutical Manufacturers Association indicates that in 1958 out of almost 115,000 substances tested, about 1,900 went on to clinical trial and about 40 of these have become or will become marketable drugs. So the failure ratio in this effort to fight against disease is 2,800 to 1. I might say that this even needs some explanation because according to the information provided to me, only about one product out of 7 can be called a profitable product.

So you see that 2,800 to 1 is misleading. It should be several times 2,800 to 1.

Senator KEFAUVER. Is this chart attached as one of your exhibits?

Dr. SMITH. It is, Senator. It is following page 8 in the manuscript.

Senator KEFAUVER. Very well.

(For chart referred to, see p. 10681.)

Dr. SMITH. Many of us recall from personal experience in our younger days how often we had only prayer and hope when illness struck, and the kindly sympathy of the physician. This has changed, and in the short period of a quarter of a century, disease after disease has been erased from the list of cripplers and killers, and as I will show you later in the presentation, there isn't any disease left to my knowledge that the pharmaceutical industry is not in some way attempting to attack today. These discoveries have been made possible in large part by the development of the drug industry and of course with

*The complete text of Part I of Dr. Smith's presentation may be found beginning on p. 10678.

the cooperation of doctors and pharmacists and others who are actively engaged in scientific fields. This is a team project. But when it comes to drug therapy, the pharmaceutical industry has taken the pioneer steps and led the way.

In years gone by when I have addressed members of the general public, I have found a great interest on their part about their hopes for the future based on knowledge of the past. I found that they are very interested for example in the fact that today they are living many years longer than they did say 40 years ago.

At the turn of the century the life expectancy was less than 50 years. Today it is almost the biblical three score and ten. I have also found that they are interested and impressed when they realize that there are millions of Americans living today who would have been dead if our Nation's death rate, such as existed roughly 25 years ago, had continued.

In fact, statistically in this room this morning, which seems filled, there probably are 11 or 12 people presently alive who would have been dead if our death rate of 1935 still existed. And I cannot help but wonder which of us might have been included in the 11 or 12.

In the next chart there is a presentation of the advances that have been made, and I would like to stress this with full recognition of the fact that this is a cooperative medical team result. You will see that these rates apply to ages that are, shall we say, susceptible to the effects of drugs. These young individuals like the older people are the ones who have diseases so commonly that fall before drugs.

And when we look at this chart and find that babies under 1 year don't die as frequently as they used to, and those a little older less frequently, I think again we have a concrete example of what that may mean to our own families, our own children and our grandchildren also.

(For chart referred to, see p. 10683.)

Dr. SMITH. The next chart is a further indication of the way diseases have fallen before the onslaught of modern medicine.

And again I emphasize these because these diseases are ones that are particularly susceptible to the effect of drugs. You can read the chart. I would not take your time, gentlemen, by repeating the words that are there. But this is concrete example of what is being done today with drug therapy.

(For chart referred to, see p. 10684.)

Dr. SMITH. I suppose that the most important contribution of the ethical drug manufacturing industry to our society has been in the field of saving human lives. As doctors, as members of the health team, as just good citizens, all of us are interested in saving lives and lessening suffering. But in addition, every major advance of the U.S. drug industry has been accompanied by astronomical dollars and cents savings to the American people.

In fact, the National Health Education Committee has reported that in just 1 year the U.S. Treasury gained more than a billion dollars and almost $6 billion was added to the national income as a result of the decline in mortality rates since 1937.

The next chart is just one example of how these savings come about for the patient suffering and for dollars. You can see what a drug

or a group of drugs can do in one field when that field is successfully approached. Instead of the heavy expenditures as suggested above the centerline, we find an entirely different picture or trend below the line.

(For chart referred to, see p. 10686.)

Dr. SMITH. Earlier this subcommittee received estimates that steroids, for example, are capable of restoring more than a million Americans to a more productive life, and it has been estimated that this alone results in a saving of about a billion dollars a year for these people. Now how does this come about?

On the basis of the record and of the information that is available, I think we can conclude that the ethical drug manufacturing industry achieves this because of its competitive nature, and I think it is one of the most competitive that has ever been examined.

There are approximately 1,300 companies manufacturing prescription drugs in this country, and yet no one company accounts for as much as 10 percent of the total sales. This certainly is a degree of competitiveness that is approached by few other industries.

It is not easy to perform such a top quality job and emerge as an industry leader, and yet the history of the drug industry is marked with the founding of new companies.

The record shows this, and I think during the testimony that has already been brought out, and I am sure will be brought out in the months to come, you will find examples or hear about examples of how this can happen in this industry.

One interesting, original study that we have been able to make in order to be of service to this subcommittee reveals that there is no increasing concentration in the drug industry, a fact that I am sure is significant to those who wonder if there are a few who dominate or could dominate a field.

Therefore, I believe that any analysis of this industry in the context of antitrust or monopoly factors should take into full account a basic characteristic which is the antithesis of that existing under monopoly conditions—the high rate of obsolescence of prescription drugs.

I suppose one way of presenting this is to say that the individual company is always attempting, so it would seem to the casual bystander, to put itself out of business by trying to find a better drug. Actually it is trying to meet the medical challenges that exist and, as a result, move onward. So in the drug industry competition forces each company as a matter of economic survival to dedicate itself to obsoleting its own products.

This is brought about with tremendous expenditures in research.

It is anticipated in 1970 the pharmaceutical industry probably will be spending between $400 and $500 million in research.

(For chart referred to, see p. 10689.)

Dr. SMITH. The next chart shows how the pharmaceutical industry compares with other industries in terms of percentage of sales dollars spent, all industries being roughly 3.2 percent, the drug industry about 9.5 percent.

(For chart referred to, see p. 10690.)

Dr. SMITH. The following chart gives some indication of the fields in which the pharmaceutical industry is active researchwise.

This is the figure, 114,000 compounds, that I mentioned earlier, that has such a low payoff, so to speak, in terms of successful agents for disease.

Yet there is no shortcut to this.

In the last year for which figures are available, the drug industry spent between 20 and 25 percent of its total research budget on fundamental research in contrast with an all-industry expenditure of only about 4 percent, a point, Mr. Senator, that I would like to mention at this time in the testimony, because there have been accusations that the drug industry is interested only in the development of new drugs.

Frankly, I think that the latter in itself is admirable because of the effect that it has on the health of the people in our country, but nevertheless, the drug industry does spend almost a quarter of its total research budget on fundamental research.

This research has a demand for very highly specialized people, and again the Pharmaceutical Manufacturers Association has determined the number of scientists that are in the drug industry, a fact which we can reveal later if time permits in questioning, but I would like to just at this time mention that this is not inexpensive.

For example, the maintenance cost for a Ph. D. scientist may run from $50,000 to $75,000 a year, including his salary and the cost of his equipment and other facilities. There are more scientists, incidentally per thousand employees in the drug industry than any other industry in the United States.

(For chart referred to, see p. 10691.)

Dr. SMITH. The next chart emphasizes my statement earlier that I like to speak of the low cost of drugs, not only because of the bargain that they provide, but because of the history of drug prices.

Dr. Jules Backman has said that if drug prices had risen as much as other prices since 1939, it would cost the consumer at least another billion dollars to buy the drug preparations now consumed.

This chart indicates how wholesale prices generally of industrial products have risen but how wholesale drug prices have been held in line during these inflationary periods.

(For chart referred to, see p. 10693.)

Dr. SMITH. The following chart very quickly shows that this has been done in spite of the increase in costs where wages alone have gone up 70 percent and construction costs 64 percent.

Aside from any humanitarian reasons, the drug industry has a solid and logical economic purpose behind its interest in reasonable prices for consumers.

Successful and profitable business operations in this industry are possible only if there is a high volume of sales in drugs, and in subsequent testimony this fact can be more fully established.

In fact already it has been explained in part in the information before you and in the documents which are now a part of the record.

(For chart referred to, see p. 10694.)

Dr. SMITH. In the following chart you will find that today the far more effective drugs which we have, which is a very important point to which I referred when I mentioned these two doctor's bags actually take less out of each individual's health dollar than they did 30 years ago.

In 1930 20 cents of each American dollar spent for health purposes went for drugs and sundries.

In 1958 it was 19.9 cents, clear evidence that the price of drugs has not risen relative to the total expenditures for medical care, and yet most importantly, today we are dealing with lifesaving measures that can be as precise and effective as the surgeon's scalpel, and not merely pain relieving or minor agents as were available 25 years ago.

And so I think as a citizen and as one interested in medical care, that when we refer to drug prices which account for about 1 penny of each person's disposal income, 1 cent for drugs, and compare this with the many pennies that are spent for other purposes, even entertainment, we should find that the American people are interested in good health and are providing good health with the aid of all the members of the health team including the drug industry at very reasonable, for very reasonable considerations.

(For chart referred to, see p. 10696.)

Dr. SMITH. In view of the attention given in these hearings to the price of prescription drugs, I believe it might be helpful to put these costs in their proper perspective. I am sure you know that the average price of a prescription today in the United States is about $3, and more than 60 percent of all prescriptions cost $3 or less.

And only about one in a hundred cost as much as $10, a point about which there is considerable confusion I am sure. But this is a matter of record. When these items are taken into consideration, we find that the actual cost of the production of a drug must include many factors, production expenses, selling expenses, research, general administrative expenses, taxes, licenses, royalties, and so on.

We have examples of industry breakdowns, Mr. Senator, which would prove this point, which can be brought out at a later time.

But I think that sometimes it is overlooked that the actual cost of a drug does not rest on the basic chemical ingredient that goes into it. There is one thing that must be stressed, and this bears on several considerations of the drug industry, one of which I will return to again in just a very few moments. The reputable drug manufacturer is very much interested in making available for the physician to prescribe for the sick person the best possible drugs that can be obtained, and I have here examples of flow charts closely typewritten of the kind of control measures that are offered for three different substances, each of which is well known to you, a tranquilizer, an aspirin preparation, and a polio vaccine.

Now if I can stand just a moment, I will show you what a flow chart looks like, not in terms of diagrams but in terms of length of enumerated steps for just a tranquilizer. Those are the steps that are required in this kind of a presentation. When it comes to aspirin, which many people I suspect assume can be made by just anyone, may I again show you the number of steps that are necessary in order to make certain that a quality drug is available?

Those are control measures.

Senator HRUSKA. Mr. Chairman?

Senator KEFAUVER. Senator Hruska.

Senator HRUSKA. I am wondering if the witness either now or at a later time would undertake to describe the size of the paper and the size of the typing or printing thereon so that the record will clearly disclose some of its physical characteristics?

Dr. SMITH. I will be glad to do that, Senator. If it is more convenient for you, we will do it just a little later for the record.

Senator KEFAUVER. Very well. When you do, it will be made a part of the record.

(The information referred to may be found on p. 10996.)

Dr. SMITH. These controls are closely related to a desire on the part of the manufacturer to make available good products, and these in turn involve normal pharmaceutical business practices, some of which I cannot by the nature of my work discuss in detail, because of lack of knowledge, and I think also because as an association man I should not.

But I would like to refer just in passing to one thing and that is the patent system which has been discussed. Patents in the United States, and certainly in the drug industry, reflect a system which provides incentives for investment of vast sums of money in endeavors which involve great risk, and this is something that cannot be overlooked.

This is an incentive for the many companies owned by hundreds of thousands of Americans who have invested their savings in drug concerns, the risk as you have seen already is great, and yet the results are to be applauded.

Obviously of course a patent system doesn't protect against failure.

Now a new discovery in itself will not cure a single living person of a single known disease unless it is made available, and no drug can accomplish anything until it is made available.

So one of the most important things that confronts the drug industry is how to obtain effective distribution.

I think—and I make this comment on the basis, Mr. Senator, or personal observation of countries throughout the world—I think there is no place in the world that has the opportunity and meets it as does the United States, which with its prescription drug industry provides educational and general information data for physicians and pharmacists and others who need it.

These are responsibilities which the drug industry is meeting. I think that they have a vital role in medical care and health as well as in the business life of the industry.

Interestingly, about 70 percent of today's prescriptions could not have been filled in 1935, and as the drug industry has grown, so has its medical care responsibilities.

And in this respect, as it has met these responsibilities, it has varied a great deal not only the kind of compound made available but often the composition of the basic drug, and the way in which it can be administered. And this to the doctor is tremendously important, because even a slight difference or some comparatively slight product improvement can be very important to the patient, the most important person to be considered in this presentation.

I have given the name competitive education and distribution to one aspect of the practices of the pharmaceutical industry, which seeks these three objectives: the supplying of medical information, which some might call education concerning new drugs, to doctors; the distribution of these new drugs; and a volume of sales that is suffi-

cient to support the first two and to finance research that will lead to tomorrow's drug discoveries.

There are three principal tools of competitive education and distribution. Two of these, advertising and direct mail, are accepted practices of a free enterprise system.

The third is unique to the drug industry, and that is the professional service representative or, as he is commonly called, the detail man.

My statement for the record contains a chart which will give you an indication of the acceptance of the presentation of information on new drugs by the medical profession, and you will see that the detail man comes first.

There are surveys, and in fact I have them, gentlemen, if they are necessary for reference, to prove that the detail man serves a very useful and very popular place in the medical care picture.

Surveys have also shown that medical journal advertisements are very important to the American physician, and again there is information that is available to support this contention, and there are some of us who could answer questions from personal knowledge and experience on the role of advertising and how it is carefully screened.

There is one other factor which I would like to mention concerning the presentation of advertisements, because again there is some confusion about this, and at a later time Mr. Senator, if there is questioning I would go into this in more detail.

Our so-called advertising is far different from the sales promotion message that the American consumer normally gets.

Ethical drug advertising has the responsibility of presenting the story about what a drug will do, what it will not do, the claims that are made for it, the dosage, and what you might call its chemical makeup. The amount of information that can be provided obviously depends on the kind of presentation offered.

In a journal advertisement there is limited space. In a brochure that is mailed directly to the physician a more complete story can be and is told. But the most important thing about medical advertising is that it brings new product information to the doctor's attention almost as soon as this new drug has been released following review by the Food and Drug Administration.

Frankly as a physician, I would regret any timelag between the availability of a new drug and its use on a sick person. Therefore, as a physician I believe these things are good for the purposes for which they are intended.

Just a couple of words more about so-called medical advertising. Very often medical advertising is confused with other things, and I think is wrongfully categorized.

For example, pharmaceutical firms very often provide educational funds as is explained in part II of this presentation and to which I will not refer, Mr. Senator, at this time.

Educational funds provide a large part of educational support for seminars, for teaching films, for closed circuit educational television and for many other purposes, even making available books and reprints which are used by the physician.

One thing bearing on this of course is a brand name. When the manufacturer, the reputable manufacturer, makes available his product, he wants it to be known in a way that identifies that product with his firm.

He is willing to stake his reputation on it. So brand names in normal business practice become so important, and so far as the drug industry is concerned, become especially important as they provide a note of confidence for the physician and for the patient.

Behind the brand name lies the reputation, the reliability and the skill of the manufacturer. I have a lengthy presentation on this because I have strong beliefs about this, gentlemen, but instead I would like to refer only to one or two points so far as brand names are concerned.

As physicians we have had experience in the United States with drugs that have been bought at what seemed a little cheaper price or for some other reason. But they did not do the job they were supposed to do.

And I have been associated in the past with offices that examined drugs and found firsthand what would or could happen.

Not uncommonly did we find some of the more questionable preparations in tablet form, for example, when taken by mouth were unchanged by the time they had passed through the body; an incredible situation really, and certainly one that is inexcusable when we are dealing with the health of the American people.

That is why, as I stated earlier, controls become so important, and that is why the firms are so anxious to identify their products, if they have any sense of responsibility, with their firm names, and they do this with brand names. I might just say that we also have information that shows similar experiences in Canada, so this is not unique to our country. I could also refer from personal observation, if time permitted, to what would transpire and what has transpired in a few other countries in which I have had a special interest.

In this connection, gentlemen, behind you on the table are charts to be displayed. In an attempt to be helpful to members of the medical profession, generic names and trade names have been adopted by pharmaceutical manufacturers, by teachers and by practitioners.

I must express regret that the sign painter unfortunately spoke of the source as "New and Unofficial Drugs." It should be New and Non-Official Drugs. On the left the chart shows generic names chosen at random by the book published by the Council on Drugs, American Medical Association. On the right are trade names. On the left are names which I think tax the memory of most of us, and on the right are names easy to remember. Now these names on the left, I would like to stress, are chosen on the request of physicians and others who are interested in proper nomenclature because it has always been contended, by the Council on Drugs, by the United States Pharmacopeia and by the International Pharmacopeia of the World Health Organization that a generic name should indicate in some way the chemical structure of the compound. In this way a physician or anyone else, if he reads the label or the literature, will have some way of knowing the nature of the substance and will be able to translate it into terms of therapeutic efficacy. When it comes to prescribing, the trade name on the right is the one that suits his con-

venience because he too is interested in time and motion, and time and motion is very important when you are seeing 25 or 30 or more patients a day.

In the next chart which will be placed on the board now, we have several examples, of which I will cite only 2 or 3, to stress this point of the matter of convenience and help to the medical profession. These names have been chosen quite by random out of a book which is generally available.

That is Naldecon. Underneath is the combination of this substance. It is a mixture. Now which is easier, the first name or these long sentences? The next one again is a single name, Donnalate tablets and underneath you will see what the physician would have to write if he did not have a brand name.

I won't belabor this point because perhaps, Mr. Chairman, there will be an opportunity to discuss this at a later time, but there is a reason for brand names, in fact, there are many other reasons which so far have not been revealed. This is the practical medical side to which I have referred so far.

Now, there is a chart in my prepared statement which indicates the various compounds that have been discovered that are effective in more recent years in various therapeutic fields, and as you know from previous testimony, there are many others areas being investigated.

Another chart in my statement reveals some of the public benefits of the competitive profit system in drugs, quite evident, but I believe quite telling for those of us interested in the free enterprise system and good health, and a happy marriage of the two of them.

Still another chart in my statement bears on something that has been discussed up to the present time I think with some misunderstanding. I would like to make clear that this chart refers to a drug which is made in these various countries that are mentioned, and not made in the United States and shipped abroad. Now I think you will find a very interesting correlation between the prices of these drugs in the various countries and the per capita income. I will not belabor this point any more. The next chart which is on display merey indicates the many people who make up America's health team, of which the drug industry is proud to be a part.

(For charts referred to, see pp. 10701, 10705, 10707, 10709, and 10711.)

Dr. SMITH. An additional chart in my statement again summarizes the trend of drug industry earnings, and incidentally there is a figure for 1959 which has just been completed where the red dots lie and you can see the trend of drug industry earnings continuing downward.

The next chart provides an opportunity to indicate what happens to drug industry profits; 56 percent is paid out in dividends, 44 percent plowed back into business, and the chart explains why this goes in. This plowback is necessary if for no other reason than this, again looking at this as a physician now.

This plowback is necessary so that an industry can meet the medical needs of this explosive population, and to provide the drugs that our expanding population needs, and that the doctors demand as they discover new elements in the medical health field.

Still another chart in my statement gives information on the comparative industry earnings rates for 1953 to 1957. This comes from a well-known institute, and as you can see, the drug industry does

not stand alone. It is grouped with industries which contribute so much to what we might call the American way of life.

(For charts referred to, see pp. 10712, 10713, and 10714.)

Mr. SMITH. Now, Mr. Chairman, you have part II of my prepared statement, which has to do with the makeup of the drug industry. This I will not discuss at this time because it is factual information and lends itself perhaps to questioning subsequently if more details are desired.

Part III presents an original study by Donald Woodward and Banks Adams to which you referred, Senator, in your earlier statement. This provides, we hope, helpful information to explain the role of the drug industry in American economics, the place of the American drug industry among other industries, and the reasons for the place that it occupies.

And I pass this by at this time rather hurriedly because there will be time for questioning when other economic discussion arises.

There are with me today a number of individuals who I believe are in a better position than I am to answer questions concerning some phases of our medical care life, if I can use that term.

These men are physicians and pharmacists and they know firsthand what their problems are and what their patients or their customers talk about.

May I just mention them by name? One individual is Dr. Frederick Thomsen, an economist whose training experience is outlined in the biographical material which you have before you.

He has prepared a statement on economic principles which are applicable to a discussion on American industries including the pharmaceutical industry.

You have that before you. And I believe, Mr. Chairman, you said that this would be a part of the record and would appear in the transcript.

Senator KEFAUVER. Yes; that's right.

Dr. SMITH. Also present are Dr. George F. Lull, of Chicago, who was formerly secretary and general manager of the American Medical Association, and prior to that he was Deputy Surgeon General of the Army.

Dr. R. B. Robins of the Robins Clinic, Camden, Ark., who is the past president of the American Academy of General Practice, a past president of the American Medical Association, currently a member of the AMA board of trusteees and, as you know, much interested in civic affairs in his part of the country.

Dr. Arthur DeGraff, cardiologist from New York City, a professor of New York University, a chairman of the Subcommittee on Scope and a member of the Committee on Revision of the U.S. Pharmacopeia, formerly a member of its board of trustees and, incidenteally, editor of GP, the official publication of the American Academy of General Practice.

Dr. Apple, secretary and general manager of the American Pharmaceutical Association, a pharmacist; Dr. Linwood F. Tice, dean of the Philadelphia College of Pharmacy and Science, a pharmacist; Mr. Grover C. Bowles, director of pharmacy service, Baptist Memorial Hospital, Memphis, Tenn., and past president of the American Society of Hospital Pharmacists, obviously a pharmacist; and Mr. George L. Scharringhausen, Jr., from Park Ridge, Ill.

Mr. Scharringhausen is from a family of pharmacists. His father was a pharmacist, Mr. Scharringhausen is a practicing pharmacist. He has a son and a daughter who are practicing pharmacists, and interestingly while he has nine pharmacists working with him in his pharmacy last October he filled his millionth prescription.

There is one additional individual who had expressed a desire to be with us today, and unfortunately something arose which prevented it, but I would like to read you just one paragraph from his letter.

He says:

> I want you to know that I would like to testify before the committee, and if you can find out just when testimony is to be taken in March and let me know, I will make an official request to Senator Kefauver for permission to appear and make a statement.

This letter is from Dr. I. S. Ravdin, surgeon from Philadelphia.

I am looking for some additional information here, Mr. Chairman, that I thought would be helpful to your committee.

In anticipation of supplying this additional information, I would like to raise for serious consideration of the subcommittee several questions because it seems to me that when we are dealing with health, we have obligations that sometimes are not apparent to those who listen to your earnest probing for information. Sometimes these individuals fail to understand the nature of the probing or the replies that are given because these replies are not always fully informative but in response to direct questions. So I would like to raise six questions that worry me.

Senator KEFAUVER. Dr. Smith, I am sorry to interrupt you at this point, but it is necessary at the present time that we go to the Judiciary Committee meeting. We will have to stand in recess and I don't know what the situation is going to be this afternoon. But we will have to keep in touch with your office and with the press and with the other Senators and the staff and try to carry on 30 minutes after the Senate adjourns.

Dr. SMITH. Mr. Senator, may I again thank you and the other members of your subcommittee for your courtesy and assure you that we will stand ready to meet your wishes and try to be helpful as you request.

Senator KEFAUVER. We want to hear you fully, so we will have to do the best we can under the circumstances.

We will stand in recess as of the present time until 30 minutes after the recess of the Senate.

If there is some other arrangement made, we will notify you.

(Whereupon, at 10:45 a.m., the hearing was recessed, to reconvene 30 minutes after the recess of the Senate.)

ADMINISTERED PRICES

TUESDAY, FEBRUARY 23, 1960

U.S. SENATE,
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:40 p.m., in the caucus room, Old Senate Office Building, Senator Estes Kefauver, presiding.

Present: Senators Kefauver (chairman), and Hruska.

Also present: Paul Rand Dixon, counsel and staff director; Horace L. Flurry, counsel; Peter N. Chumbris, counsel for minority; Nicholas N. Kittrie, counsel for minority; Lucile B. Wendt, attorney; Dorothy D. Goodwin, attorney; Bushrod Howard, attorney; Dr. John M. Blair, chief economist; Dr. E. Wayles Browne, Jr., economist; Dr. Irene Till, economist; Herschel Clesner, special consultant; Paul S. Green, editorial director, and Gladys E. Montier, clerk.

EVENING SESSION

Present: Senators Kefauver and Hruska.

Senator KEFAUVER. The committee will come to order. I want to say again that while this committee has had night sessions in the past, we are sorry the circumstances make it necessary at this time. But as I stated this morning, some days ago Senator Dirksen said that he would object to the committee sitting while the Senate was in session—which is his right if he wants to be both places—so we have had no alternative but to recess this morning. I felt that because of the witnesses we had scheduled, and the fact that a number of distinguished physicians were here from out of town, it was only fair to try to carry on tonight as far as we could.

We had planned in the morning to schedule some witnesses from Consumers Union but they have agreed to come later in the week. So we will have a short time tomorrow morning to conclude with Dr. Smith and any of the physicians and other gentlemen with him. I will ask a few preliminary questions and then other members of the committee will ask any questions they wish to at this time, and then I will turn to our chief counsel, Mr. Dixon, for his questions.

Had you finished your statement, Dr. Smith?

STATEMENT OF DR. AUSTIN SMITH, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ACCOMPANIED BY JOHN K. WORLEY, GENERAL COUNSEL, DR. WILLIAM S. APPLE, GROVER C. BOWLES, DR. ARTHUR C. DE GRAFF, DR. GEORGE FAIRLESS LULL, DR. RUFUS B. ROBINS, GEORGE L. SCHARRINGHAUSEN, JR., DR. FREDERICK L. THOMSEN, AND DR. LINWOOD F. TICE—Resumed

Dr. SMITH. I have just an additional statement, a short one, Mr. Senator, to include in the record, and if I may, it will take just three or four moments to read.

Senator KEFAUVER. Very well.

Dr. SMITH. As a final part of my statement, I would like to announce now several items which are another indication of the pharmaceutical industry's deep awareness of its obligations as good citizens as well as good businessmen. Some of these have been under consideration for some time, others for a longer period, others for a shorter period, and I would like to enumerate these nine items. First, the Pharmaceutical Manufacturers Association——

Senator KEFAUVER. Is this part of your statement or is this additional?

Dr. SMITH. I am giving additional information, sir.

Senator KEFAUVER. Do you have copies of it?

Dr. SMITH. I will see that they are available, sir. First, the Pharmaceutical Manufacturers Association has under study the organization of an expert committee to study continuously and to report from time to time trends and factors influencing such trends in medical care costs as far as they are related to use of drugs.

Second, the Pharmaceutical Manufacturers Association has "seeded" for several years a clinical pharmacology program in this country to interest scientists in clinical pharmacology. It now is studying how to undertake a similar "seeding" program to interest scholars in medical economics, similar to its established program with regard to clinical pharmacologists.

Third, the Pharmaceutical Manufacturers Association is studying how to encourage and anticipate in an educational program to prevent accidents to children who find drugs carelessly placed in homes and elsewhere.

Fourth, PMA is studying how it can encourage more people to enter medical service and the medical field.

Fifth, the PMA is attempting to determine how it can be continuously appraised of the areas of disease and discomfort so that its members can assess how if at all they can increase their efforts to bring relief from suffering and disease.

Sixth, the PMA has been considering a program by which it, through setting an example, could encourage the bringing of physicians from less well-developed areas to learn how to use drugs in patients for whom in their countries there often are no hospitals, in fact not even adequate treatment facilities.

And as you know, the pharmaceutical industry long has been interested in such projects as Project Hope.

Seventh, the PMA board of directors has authorized appointing a committee to meet with other groups to study the relationship of prescription drug needs to other medical care needs of the indigent and the elderly. This is a social problem that reflects wants extending far beyond the narrow boundaries set by prescription drug needs.

Eighth, the PMA has authorized a continuing study of the role of drugs in domiciliary care to ease the burden on hospitals.

Ninth, the PMA has authorized a program for studying the role of drugs in special situations, for example driving and rehabilitation and accident-prone people.

Now here, Mr. Chairman, are just 9 items of interest to the PMA, an organization not yet 2 years old but one with a background of study and service that already has resulted in the formation of 60 to 80 committees, and I would hope, sir, that this would demonstrate for those who are interested in the facts that the pharmaceutical industry of the United States of America has expressed through the members of the PMA a deep awareness of its obligations.

That would conclude, sir, the presentation of at least this portion of my statement.

Senator KEFAUVER. Very well, sir. Dr. Smith, when we started this morning there were certain preliminary matters that I should have properly asked you but didn't.

First, in the letter that you have given me I find the bibliography of the various physicians and pharmacists who are with you. I don't find yours. Is yours included?

Dr. SMITH. Mine is in part I of the statement which was filed with the committee yesterday. It is a brief biographical sketch.

Senator KEFAUVER. Oh, yes, I see. You received your M.D. and C.M. degree in 1938 from Queens University, Ontario, is that correct?

Dr. SMITH. That is right, Mr. Chairman.

Senator KEFAUVER. And your master's degree in science from the same institution in 1940?

Dr. SMITH. That's right.

Senator KEFAUVER. And you practiced medicine, I take it, in Ontario?

Dr. SMITH. I am licensed to practice in Ontario and I served as a consultant while doing research and teaching there before I went to New York.

Senator KEFAUVER. Did you practice medicine in Ontario?

Dr. SMITH. No, only as a consultant.

Senator KEFAUVER. And then you went to New York in what year?

Dr. SMITH. In 1939.

Senator KEFAUVER. What did you do when you got to New York?

Dr. SMITH. There I served an internship and did some research in certain phases of medicine I was interested in, particularly endocrinology and the water balance of the body.

Senator KEFAUVER. In what hospital?

Dr. SMITH. Yonkers General Hospital, New York.

Senator KEFAUVER. I believe from 1942 to 1949 you were secretary of the Council on Pharmacy and Chemistry. What is that?

Dr. SMITH. I suppose I can describe it best as a drug-evaluating body. It is now known as the Council on Drugs. It changed its name 2 or 3 years ago.

Senator KEFAUVER. Then from 1946 to 1949 you were the director of the Division of Therapy and Research of the American Medical Association.

Dr. SMITH. That's right, sir.

Senator KEFAUVER. Where were you located then?

Dr. SMITH. In Chicago.

Senator KEFAUVER. Then from 1949 to the end of 1958 were you editor and managing publisher of the Journal of the American Medical Association?

Dr. SMITH. And AMA scientific publications, that's right.

Senator KEFAUVER. Are you licensed to practice in this country?

Dr. SMITH. No; in Ontario, Canada.

Senator KEFAUVER. Only in Canada?

Dr. SMITH. That's right.

Senator KEFAUVER. I believe you became an American citizen in 1943?

Dr. SMITH. That's right.

Senator KEFAUVER. You say the Pharmaceutical Manufacturers Association is 2 years old?

Dr. SMITH. That's right.

Senator KEFAUVER. Are you the first president of it?

Dr. SMITH. No.

Senator KEFAUVER. Who is?

Dr. SMITH. I am the first full-time president.

Senator KEFAUVER. Who was your predecessor?

Dr. SMITH. Mr. George F. Smith.

Senator KEFAUVER. That is Mr. Smith of Schering?

Dr. SMITH. Of Johnson & Johnson.

Senator KEFAUVER. When did you take over as president?

Dr. SMITH. In April 1959.

Senator KEFAUVER. The Pharmaceutical Manufacturers Association is composed, you said, of 130-odd pharmaceutical manufacturers?

Dr. SMITH. That's right.

Senator KEFAUVER. Are they all in the ethical field or are some in the proprietary field?

Dr. SMITH. No, they all make prescription items.

Senator KEFAUVER. But some make proprietary items also?

Dr. SMITH. No, a few might have subsidiaries, but these are manufacturers which make items that are available usually only on prescription, although some under the Federal Food, Drug, and Cosmetic Act can be sold across the counter, but even then, these firms advertise to physicians and not to the consumer.

Senator KEFAUVER. Will you supply the committee, and we will make it a part of the record, with a list of the members of the Pharmaceutical Manufacturers Association?

Dr. SMITH. Yes, sir.

Senator KEFAUVER. Is the Pharmaceutical Manufacturers Association composed of the large drug companies we have had before us such as Schering, Merck, Upjohn, Smith Kline & French, American Home and others?

Dr. SMITH. Yes, they are included as members. There are many others too, but they are not all large manufacturers. They range I believe probably from $100,000 annual volume up.

Senator KEFAUVER. You say they range from $100,000 and up?
Dr. SMITH. Yes.
Senator KEFAUVER. Are such companies as Olin Mathieson members, or is the member their subsidiary Squibb?
Dr. SMITH. Squibb is a member.
Senator KEFAUVER. What is the budget of the PMA?
Dr. SMITH. Roughly a half million dollars.
Senator KEFAUVER. A year?
Dr. SMITH. Yes, sir.
Senator KEFAUVER. What is your salary?
Dr. SMITH. $45,000 a year.
Senator KEFAUVER. Is Dr. Apple your executive director?
Dr. SMITH. Oh, no.
Senator KEFAUVER. He is with the American Pharmaceutical Association?
Dr. SMITH. Yes. I would be proud if he were with me.
Senator KEFAUVER. Your counsel is Mr. Worley?
Dr. SMITH. Yes, Mr. John K. Worley.
Senator KEFAUVER. He is the executive director of the Pharmaceutical Manufacturers Association?
Dr. SMITH. There are two executive officers associated with me. One is the executive vice president, Dr. Karl Bambach. The other is the administrative vice president, Dr. John Closs.
Senator KEFAUVER. Is this budget of $500,000 a year your current 1959 budget?
Dr. SMITH. Yes. It is a little more than that. I would have to look up the figures, but it is in the neighborhood of $500,000.
Senator KEFAUVER. What is the spent for, just your general expenses?
Dr. SMITH. For the work of the association which is primarily scientific and in part trade. This is a combination professional organization and a trade organization, and the money is spent for the scientific pursuits and the organizational activities of the association.
Senator KEFAUVER. Do you ordinarily employ public relations consultants?
Dr. SMITH. Do we ordinarily?
Senator KEFAUVER. Yes.
Dr. SMITH. Well, we have only been in existence 2 years.
Senator KEFAUVER. The press has said that you entered into a contract with Hill & Knowlton for $200,000, in connection with this hearing, for 1 year.
Dr. SMITH. I don't know where the press could possibly have gotten such information as that, because it is not true.
Senator KEFAUVER. Have you employed them?
Dr. SMITH. Yes, they are retained as counsel but not for these hearings. They were retained as counsel following a very careful search of public relations counsel over a period of months to advise concerning the general public relations program for the PMA.
Senator KEFAUVER. When were they retained?
Dr. SMITH. About 3 or 4 months ago.
Senator KEFAUVER. What is their compensation?
Dr. SMITH. They are on a retainer of $5,000 per month.
Senator KEFAUVER. And extras in addition to that?

Dr. SMITH. Incidental out-of-pocket expenses, and if there is any printing or something like that, of course, they would be reimbursed for those expenses.

Senator KEFAUVER. You don't employ lawyers?

Dr. SMITH. Mr. Worley is general counsel.

Senator KEFAUVER. Well, he is a good lawyer. I mean, you don't employ outside lawyers?

Dr. SMITH. No, sir.

Senator KEFAUVER. On what basis are your members assessed for dues?

Dr. SMITH. The amount of the payment is according to the volume of business, and in the book which was filed with you, the certificate of incorporation and bylaws of the Pharmaceutical Manufacturers Association, there is a reproduction of this table.

Senator KEFAUVER. Do you have the table there?

Dr. SMITH. Yes, sir.

Senator KEFAUVER. We don't have that in the record.

Dr. SMITH. It was filed.

Senator KEFAUVER. But in general, is it on the basis of the sales of the company?

Dr. SMITH. Yes, annual business.

Senator KEFAUVER. On what percentage of sales?

Dr. SMITH. Well, this would run from roughly $300 to approximately $16,000 for the volume of business which might be less than $100,000 or more than $140 million.

Senator KEFAUVER. $300 for the small companies and up to $15,000 for the large ones?

Dr. SMITH. Yes.

Senator KEFAUVER. We notice from the table you filed that Merck, for instance, is listed several times—Merck & Co.; Merck Chemical Division; Merck Sharp & Dohme.

Does that mean that each one of them is a separate member?

Dr. SMITH. May I ask Mr. Worley to reply to the membership?

Mr. WORLEY. So that these separate divisions may have representations on the sections, Mr. Chairman, there is provision for separate listing. They all pay on the same basis, but for a separate listing, which roughly covers the cost of mailings and maintenance and so forth, it is $300 a year, I believe.

Senator KEFAUVER. Do they have three votes or 4 votes depending on how many divisions they have?

Mr. WORLEY. No. In the bylaws and the articles you have on file, there is only one vote per company.

Senator KEFAUVER. No matter how many divisions it might have?

Mr. WORLEY. That's right.

Senator KEFAUVER. And a big company has the same vote as a little company?

Mr. WORLEY. That's right, Senator.

Senator KEFAUVER. How are they selected to be members of the PMA?

Mr. WORLEY. They are not selected. They apply for membership.

Senator KEFAUVER. If they apply for membership, how are they brought into the association?

Mr. WORLEY. The bylaws have a very explicit outline of membership qualifications. The application is processed by a committee on membership of the board of directors. Then the board of directors passes on the member and then the full membership at the next meeting. That is the general process.

Senator KEFAUVER. Does it take a majority vote, can one company blackball a new applicant, or how does it happen?

Mr. WORLEY. Frankly in 2 years we haven't been faced with that.

Senator KEFAUVER. Premo said that it applied for membership and was turned down.

Dr. SMITH. Premo has not applied for membership in the Pharmaceutical Manufacturers Association.

Senator KEFAUVER. They testified, as I remember it, that they had.

Dr. SMITH. I'm sorry, but the records do not show that.

Mr. WORLEY. I was here then, Senator. I believe they said——

Senator KEFAUVER. Then they had applied to the predecessor organization. What was the predecessor organization?

Mr. WORLEY. American Pharmaceutical Manufacturers Association, I believe is the one that applied to.

Senator KEFAUVER. They said they applied on three different occasions. Does PMA carry on the same arrangement as the American Pharmaceutical Manufacturers Association?

Mr. WORLEY. No; I think it is entirely different, Senator.

Senator KEFAUVER. Did the American Pharmaceutical Manufacturers Association go out of business?

Mr. WORLEY. They are still in existence, but have an inactive status. Technically they are in existence to hold the same name so that somebody else will not capture it and embarrass us.

Senator KEFAUVER. But your Pharmaceutical Manufacturers Association took over their work?

Mr. WORLEY. That is right.

Senator KEFAUVER. And their staff and their duties?

Mr. WORLEY. Not the entire staff because that was part of the economy move in the joining together.

Senator KEFAUVER. You are the true successor of the American Pharmaceutical Manufacturers Association?

Mr. WORLEY. I believe that is so; yes.

Senator KEFAUVER. You mean that if Premo should apply to you, they might get a different response than they did from the American Pharmaceutical Manufacturers Association, Dr. Smith?

Dr. SMITH. This is a matter, Mr. Chairman, that would be reviewed by the membership committee and by the board of directors and the full membership.

I can't say except to say that anyone is free to make application. I would like to mention just one thing in the event there is misunderstanding. There were two organizations, the American Pharmaceutical Manufacturers Association and the American Drug Manufacturers Association that had membership which subsequently became membership in the PMA.

Senator KEFAUVER. Yes; I think you said that there were about 1,300 pharmaceutical manufacturers now in the United States.

Dr. SMITH. Yes.

Senator KEFAUVER. I believe you have 130 in your organization?

Dr. SMITH. Between 130 and 140.

Senator KEFAUVER. And the smaller ones just pay $300, you said. What keeps the rest out? Why aren't they all members?

Dr. SMITH. I don't know. They just haven't applied.

Senator KEFAUVER. Isn't this an important right to be a member of the Pharmaceutical Manufacturers Association?

Dr. SMITH. It is a privilege like membership in a professional association. If you are qualified then you become a member.

Senator KEFAUVER. This is the association that deals with the U.S. Pharmacopoeia and the Food and Drug Administration?

Dr. SMITH. Oh, yes.

Senator KEFAUVER. In classifying drugs?

Dr. SMITH. We work cooperatively with all branches of government.

Senator KEFAUVER. So if they are not members, they don't have a real voice in the dealings that you have with the USP and the Food and Drug Administration? Very well.

What is the National Pharmaceutical Council?

Dr. SMITH. Well, I am not familiar with it except as a name, and I know some of the personnel. I just don't know its makeup or much about it.

Senator KEFAUVER. Isn't it financed by the Pharmaceutical Manufacturers Association?

Dr. SMITH. I don't know what the financial arrangements are.

Senator KEFAUVER. Is it financed by you?

Dr. SMITH. Mr. Worley says it is not financed by us.

Mr. WORLEY. We make no contribution to it. Individual member firms may, Senator.

Senator KEFAUVER. It is also financed by the drug companies, is that true?

Mr. WORLEY. I am in the same position that Dr. Smith is. I don't know the details, but I know that we make no contribution to the NPC.

Senator KEFAUVER. Do you work with the National Pharmaceutical Council?

Dr. SMITH. No.

Senator KEFAUVER. What is the Health News Institute?

Dr. SMITH. The Health News Institute is an organization designed to disseminate information on health matters concerning the whole health team to those who are interested in these broad health matters.

Senator KEFAUVER. Are you the president of that?

Dr. SMITH. I am.

Senator KEFAUVER. Do you get a salary from that also?

Dr. SMITH. No.

Senator KEFAUVER. Then that is part of the work of the PMA?

Dr. SMITH. No. Because it feels that it is important to disseminate information on health matters, PMA has assumed a responsibility for this, but I am not its president because I am president of the PMA.

Senator KEFAUVER. The Health News Institute, though, is part of the work of the PMA?

Dr. SMITH. No; it is a separate organization.

Senator KEFAUVER. But it is financed by the PMA?

Dr. SMITH. It is now.

Senator KEFAUVER. It used to be independent?

Dr. SMITH. It still is independent. This is a grant made by the PMA.

Senator KEFAUVER. Is it wholly financed by the PMA?

Dr. SMITH. It is now.

Senator KEFAUVER. And you are the president of the Health News Institute?

Dr. SMITH. That's right.

Senator KEFAUVER. It puts out a newsletter and statements and whatnot?

Dr. SMITH. From time to time it publishes news releases on various subjects ranging from the need for poliomyelitis vaccination to the need for drinking pure water.

Senator KEFAUVER. And it employs science writers?

Dr. SMITH. There are two individuals who are qualified to write such material.

Senator KEFAUVER. Who are they?

Dr. SMITH. Their names are Woodward and Mashburg.

Senator KEFAUVER. Then what is the Health Information Foundation?

Dr. SMITH. Well, the Health Information Foundation is an independent organization that is designed to gather information in the health care field as a whole to determine what the health needs are, and is mentioned in part II of the document which was filed with you because of industry's contributions to this Foundation.

It is a means of gathering information on medical care needs. It works closely with medical organizations and others and is heavily supported by members of the drug industry and others.

Senator KEFAUVER. What is the connection, if any, between the PMA and the Health Information Foundation?

Dr. SMITH. There is none.

Senator KEFAUVER. Are you connected with the Health Information Foundation?

Dr. SMITH. No, not at all.

Senator KEFAUVER. Does the World Medical Organization have any connection with the Pharmaceutical Manufacturers Association?

Dr. SMITH. The World Medical Association?

Sentor KEFAUVER. Yes, the World Medical Organization, or association.

Dr. SMITH. Association. There is a U.S. supporting committee as there are supporting committees in various countries throughout the world, which is supported in part from several sources including individual contributions from firms, membership by doctors and other groups.

Senator KEFAUVER. In part I of your statement you said that you are chairman of the board of directors of the United States Committee and Council Emissary of the World Medical Association.

Dr. SMITH. That is quite right. I was chairman of the board when I was with the American Medical Association.

Senator KEFAUVER. And you continued on in that position?

Dr. SMITH. Yes, council Emissary was an appointment of rather recent date. Prior to that I was editor of the World Medical Journal and prior to that a member of the Council of the World Medical Association.

Senator KEFAUVER. Is this composed of pharmaceutical companies throughout the world?

Dr. SMITH. No, the membership consists of national medical associations from the free part of the world.

A membership in the World Medical Association is based on the National Medical Association, the doctors who are members of the National Medical Association are members of the WMA by virtue of that so that its membership is roughly 700,000.

Senator KEFAUVER. You are now the executive editor of the World Medical Journal?

Dr. SMITH. No, I resigned that position some time ago.

Senator KEFAUVER. But you did serve in that capacity?

Dr. SMITH. Yes, I did for 3 or 4 years.

Senator KEFAUVER. Mr. Apple is with the American Pharmaceutical Association, is that correct?

Dr. SMITH. Yes.

Senator KEFAUVER. And these other physicians here with you are not connected with the Pharmaceutical Manufacturers Association?

Dr. SMITH. No.

Senator KEFAUVER. They are members of various organizations. Do they speak for these organizations?

Dr. SMITH. No, I am sure they don't, but only they could say.

Senator KEFAUVER. Why are they here?

Dr. SMITH. They are here, Senator, because I asked them if they would be willing to express their opinions about some of the subjects that have been discussed in the past and are of interest to this subcommittee and to me.

It was my feeling, and these men concurred, that their experience made them much better qualified than I to discuss some of the practical areas into which the discussions might dip, and so they have offered to be helpful to the subcommittee if it is your wish.

Senator KEFAUVER. So they are here in their capacity as individuals and not representing any organization?

Dr. SMITH. That's right, sir.

Senator KEFAUVER. Dr. Smith, part I of your statement, which you have given and which we will get into shortly, you have listed about 54 sources of information.

Dr. SMITH. Yes, sir.

Senator KEFAUVER. About half of these appear to be from organizations in the drug industry itself. For instance, you list information, charts or documents from the Health News Institute, of which you are the president and which is financed by the PMA. However, there are other documents and other references to your source of material. Will you submit such underlying sources of material so we can examine them?

Dr. SMITH. We will be delighted to do so.

Senator KEFAUVER. Do you have them here?

Dr. SMITH. No, I don't. I may have some of it in the box here but I don't have all of it. It is a mass of material.

Senator KEFAUVER. Do you have the document dated December 1959, of the Health Information Foundation which you referred to? It is a brief review from the year 1920 to the present which you have used as source material in your statement on several occasions.

Dr. SMITH. I'm not sure; I can look for it if you would like.

Senator KEFAUVER. If you will, please.

Dr. SMITH. May I ask again which volume it is, Mr. Senator?

Senator KEFAUVER. The date is December 1959.

Dr. SMITH. The ones that I have here are publications. Which reference is that in the list of references cited in the text?

Senator KEFAUVER. I will have to check your statement.

Mr. DIXON. Do you have the December 1959 document with you?

Dr. SMITH. I can't identify the document by date. There may have been several documents. Can you give me a title?

Mr. DIXON. The title is "A Brief Review From 1920 to the Present."

Dr. SMITH. The private expenditures for drugs and other components of medical care?

Mr. DIXON. That is right.

Dr. SMITH. Yes; I have that.

Senator KEFAUVER. May we see that, please?

Dr. SMITH. Certainly.

Senator KEFAUVER. We have been discussing profits both on net worth and on sales. For those figures we have used the Federal Trade Commission largely, and we have had tables based upon the Fortune magazine listings with which you are familiar. You base your figures on Stanford Research Institute, and they seem to be different from the Federal Trade Commission and from the Fortune listings. Do you have the Stanford Institute material with you?

Dr. SMITH. We have material. I am not sure if I have the complete document, but I would like to call on Dr. Thomsen to be of assistance to the subcommittee in this respect.

Senator KEFAUVER. Just give us the basic material. For instance, on one of the charts of the Stanford Research Institute, industries are listed earning 10 to 15 percent.

Dr. SMITH. Yes.

Senator KEFAUVER. Ethical drugs is listed. But we don't know whether that is before taxes, after taxes, or on total capital. Does that mean net worth, investment, or what does it mean?

Dr. SMITH. This is the net profit.

Senator KEFAUVER. After taxes or before taxes?

Dr. SMITH. After.

Senator KEFAUVER. The Federal Trade Commission figures showed about 22 percent after taxes. We would like to see the basic document on which you base your figures.

Dr. SMITH. This we have here, and I believe, Mr. Senator, that it would be more really helpful to you and the members of the committee if Dr. Thomsen was permitted to give you some information on this score.

Senator KEFAUVER. May we see what you have there, please?

Dr. Thomsen, can we ask you a brief question about what this is based on? The survey of the Stanford Research Institute of September 1959, which I now see for the first time, lists proprietary drugs at 20.5 percent, as the average rate 1953–57. Ethical drugs is

shown at 14.6 percent. Proprietary drugs is second highest, and ethical drugs is fifth highest on the table that you have here, on the average. How does Stanford separate proprietary drugs from ethical drugs? Some companies make both.

Dr. THOMSEN. May I say that the material that you have there is not the result of a formal study on which a published report has been made. It was used because it represented a later period.

Originally a study was made by faculty members of Emory University, and the study by Cottle & Whitman. The material that you have there was prepared by one of the authors of that report who is now with Stanford, the Stanford Research Institute.

That is the only copy of it that I have. It was used by Dr. Smith because it represented a later period.

The Cottle & Whitman study, which is more complete and which we would be glad to show you, ends with 1955. And this material that I gave you was received and is not a part of any formal study. It is just material that the Stanford Research Institute put out and he used that because it was of a later date.

Senator KEFAUVER. You say it is not a part of any formal study. We presented at these hearings the Federal Trade Commission figures, and also the Fortune magazine figures, which show the drug industry at the top of the list. What you have introduced here is for the purpose of rebuttal, I suppose. But you say it is not any formal material that you have?

Dr. THOMSEN. It is material that you have in your hands; it is obtained from that.

Senator KEFAUVER. This is not a formal statement, or what is this?

Dr. THOMSEN. It is not a formal study.

Senator KEFAUVER. Not a formal study?

Dr. THOMSEN. Not a part of a formal study. It is material put out by the Stanford Research Institute, and was put in, in Dr. Smith's statement, merely because it was for a later date.

Senator KEFAUVER. This is for 1953–57. It is not later than what we have had?

Dr. THOMSEN. No, but later than the Cottle & Whitman study which was prepared earlier and which is much more complete, and we would be glad to show it to you if you have not seen a copy; if your staff has not, we would be glad to show them a copy.

Senator KEFAUVER. Does the Stanford Research Institute stand behind this as an authentic study?

Dr. THOMSEN. Presumably so, since they issued it, yes, sir.

Senator KEFAUVER. On profits in this industry?

Dr. THOMSEN. Yes; I am not acquainted with the background of the Stanford Research Institute's work which resulted in those particular figures. They were used merely because they were later than the figures——

Senator KEFAUVER. Do you and Dr. Smith consider a document that you don't know much about, that is not a formal study, that is not as late as the Federal Trade Commission figures and the Fortune figures, that they are wrong and this survey is right?

Dr. THOMSEN. No. My own opinion is that none of the data representing the ranking of industries by profit margins mean anything in relation to drug prices, for reasons which I have explained in my statement.

Senator KEFAUVER. We will go into that later, but what we want to get is the accurate figure for drug profits. You say that none of the data you just mentioned mean anything on drug prices. They certainly do. I disagree with you there. But what I am trying to get at is why you endeavor to refute the Federal Trade Commission and Fortune? The Federal Trade Commission is supposed to be an authentic source and so is Fortune, though they take a little different reference. They base their figures on investment rather than net worth.

Do you say that they are wrong and that this is right?

Dr. THOMSEN. No. I think that the differences arises because of the differences in the periods covered.

Senator KEFAUVER. This is 1953 to 1957. What was it in 1957?

Dr. THOMSEN. We have only those figures from the Stanford Research Institute.

(The Stanford report referred to, later designated exhibit 231, may be found on page 10954.)

Senator KEFAUVER. You mean these?

Dr. THOMSEN. Those figures that I gave you.

Senator KEFAUVER. And you would endeavor to put these up against the Federal Trade Commission?

Dr. THOMSEN. No, no endeavor at all to refute the other figures.

Senator KEFAUVER. That is what you are doing with your charts.

Dr. THOMSEN. No. We offer those as having been issued by a reputable organization, the Stanford Research Institute. If somebody else prefers the Fortune magazine figures, they can accept those figures. All of the figures are subject to differences because of differences in the time period covered, because profit margins have varied over the years. They also vary as among different firms in each one of the industries covered, and samples differ, samples of firms used in compiling the industry figures differ because of that.

Senator KEFAUVER. I don't want to be contentious about the matter, but Dr. Smith in his statement made quite a point that drug profits were not as high as we have been talking about and so forth. This is your source, and you say it is not a formal source?

Dr. THOMSEN. I don't think he made any statement, that I recall at least, which said that he uses that for any such purpose.

He merely presented those figures as indicative of relative profit margins in the various industries. Others may use other figures from other sources which they may consider better. And it depends on the sample of companies included and the period of time covered, and you will get different results from different studies or different compilations because of that.

Senator KEFAUVER. All right. How many companies are included in this Stanford Research Institute report?

Dr. THOMSEN. I do not know, sir, the only information that I have——

Senator KEFAUVER. Do you know what companies are included?

Dr. THOMSEN. The only information that I have regarding the study is in the material which has been submitted to you.

Senator KEFAUVER. Do you know which companies are included?

Dr. THOMSEN. No, sir.

Senator KEFAUVER. Do you know whether they include all of Olin Mathieson, for instance, which makes a very small profit, or whether they just include the Squibb subsidiary, the drug division, which makes a large profit?

Dr. THOMSEN. I believe that since the compilation was put out by the Stanford Research Institute, and since Mr. Cottle, who was the coauthor of the very extensive study entitled "Corporate Earning Power and Market Valuation 1935–55," they probably are approximately the same sample included in the Cottle and Whitman study, which I can turn over to you to show you the ones that also were included in that study.

Senator KEFAUVER. Do you know that to be true?

Dr. THOMSEN. No, I am not certain of that.

Senator KEFAUVER. I wonder why you take a document that you say is not a formal study, you don't know what it is and you attempt to rebut the findings of the Federal Trade Commission.

Dr. THOMSEN. There was no attempt to rebut the findings of the Federal Trade Commission, Senator, or of Fortune magazine. It is merely a different sample covering a different period of years.

Senator KEFAUVER. No, they don't cover different years. This covers average rate, 1953–57. It doesn't say what it is in any of these particular years. Do you have the Stanford study there?

Dr. THOMSEN. No, but I have the one made at Emory University by the man who has now gone to Stanford, to the Stanford Research Institute.

Senator KEFAUVER. It so happens we have the Stanford study here to which you refer. In the ethical drug field the authors include only three drug companies, Merck, Parke, Davis, and Abbott Laboratories, and in proprietary drugs include only three, American Home Products, Sterling Drug and Vick-Chemical. In many of these other categories they have only two, three or four companies.

Do you think that is a good picture of the drug industry, or a better representation than by the Federal Trade Commission and by Fortune?

Dr. THOMSEN. Not necessarily. I do say this: That the Cottle and Whitman data were compiled carefully, that it appears to be a very good study. I used it for my work because other data were available for the same companies, I mean for the same industries, including the same companies.

I would be happy to turn over the Cottle and Whitman study to your staff so that they can see it.

Senator KEFAUVER. Do you think that table 37 on page 97 which includes three companies in proprietary drugs and three in ethical drugs represents a good cross section of the drug industry?

Dr. SMITH. Mr. Senator, could I comment on this? I am not an economist, but I think——

Senator KEFAUVER. I am asking Dr. Thomsen——

Dr. SMITH. I believe I have information which will help.

Senator KEFAUVER. Whether that represents a good cross section of profits. Parke, Davis had falling profits during 1955 because of troubles with Chlormycetin. That only left two companies that you were——

Dr. THOMSEN. There are four companies in the Cottle study for ethical drugs, and there are three for proprietary. The ones for ethical are Abbott Laboratories, Merck & Co., Parke, Davis & Co. and Squibb.

Senator KEFAUVER. We don't see Squibb on table 37 that we have here.

Dr. THOMSEN. I am giving you one from the Cottle and Whitman study. The Cottle and Whitman study, that is found on page 6, page 6 of the Cottle and Whitman study.

Senator KEFAUVER. What page?

Dr. THOMSEN. Page 6 of the Cottle and Whitman study. I don't know whether that is the one that you have. I think it probably is, yes.

Senator KEFAUVER. This states that Squibb has been merged with Olin Mathieson Chemical Corp. That was back in 1952.

Dr. THOMSEN. Yes.

Senator KEFAUVER. So you only have three companies left.

Dr. THOMSEN. That is right, for that period, for the period you have there in this chart.

Senator KEFAUVER. We will put table 37 in the record and let the people judge for themselves as to which is more adequate and more representative information.

(The table referred to follows:)

TABLE 37.—*Consumers' nondurable goods group—Total capital and net sales, by industries and companies, 1955*

[In millions]

Industry and company	Total capital		Net sales	
	Company	Industry	Company	Industry
Oil:				
Standard Oil Co. (New Jersey)	$5,659.9		$6,272.4	
Standard Oil Co. (Indiana)	2,038.6		1,781.3	
Socony Mobil Oil Co., Inc.	2,017.8		1,721.0	
The Texas Co.	1,814.6		1,767.3	
Gulf Oil Corp.	1,684.4		1,895.7	
Standard Oil Co. of California	1,533.2		1,277.8	
Sinclair Oil Corp.	1,064.6		1,110.1	
Phillips Petroleum Co.	1,008.8		910.8	
Shell Oil Co.	932.2		1,484.1	
Total		$17,754.1		$18,220.5
Percent of group		(66.5)		(45.0)
Rubber:				
Goodyear Tire & Rubber Co.	608.0		1,372.2	
Firestone Tire & Rubber Co.	463.6		1,114.9	
U.S. Rubber Co.	390.7		925.5	
B. F. Goodrich Co.	382.7		755.0	
Total		1,845.0		4,167.6
Percent of group		(6.9)		(10.3)
Cigarette:				
The American Tobacco Co.	621.4		1,090.8	
R. J. Reynolds Tobacco Co.	479.9		866.4	
Liggett & Myers Tobacco Co.	361.8		547.0	
Total		1,463.1		2,504.2
Percent of group		(5.5)		(6.2)

TABLE 37.—*Consumers' nondurable goods group—Total capital and net sales, by industries and companies, 1955*—Continued

Industry and company	Total capital		Net sales	
	Company	Industry	Company	Industry
Distilling:				
Distillers Corp.-Seagrams Ltd.	415.3		735.7	
National Distillers Products Corp.	344.8		500.2	
Schenley Industries, Inc.	342.5		411.7	
Hiram Walker-Gooderham & Worts Ltd.	173.8		341.3	
Total		1,276.4		1,988.9
Percent of group		(4.8)		(4.9)
Textile fabric:				
Burlington Industries, Inc.	343.3		512.2	
J. P. Stevens & Co., Inc.	215.9		321.1	
United Merchants & Manufacturers, Inc.	135.2		341.8	
M. Lowenstein & Sons, Inc.	133.4		228.2	
Cannon Mills Co.	113.9		193.7	
Total		941.7		1,507.0
Percent of group		(3.5)		(3.9)
Meat packing:				
Swift & Co.	418.0		2,404.1	
Armour & Co.	360.8		1,967.7	
Wilson & Co., Inc.	92.2		650.5	
The Cudahy Packing Co.	43.4		308.1	
Total		914.4		5,330.4
Percent of group		(3.4)		(13.2)
Dairy products:				
National Dairy Products Corp.	375.4		1,260.2	
The Borden Co.	257.1		810.1	
Total		632.5		2,070.3
Percent of group		(2.4)		(5.1)
Toilet preparations and soap:				
The Procter & Gamble Co.	401.6		965.8	
Colgate-Palmolive Co.	156.5		285.6	
Total		558.1		1,251.4
Percent of group		(2.1)		(3.1)
Packaged foods:				
General Foods Corp.	281.2		931.1	
Standard Brands, Inc.	128.9		400.7	
Total		410.1		1,331.8
Percent of group		(1.5)		(3.3)
Ethical drug:				
Merck & Co., Inc.	136.3		157.9	
Parke, Davis & Co.	88.7		123.1	
Abbott Laboratories	71.7		91.7	
Total		296.7		372.7
Percent of group		(1.1)		(.9)
Grain mill products:				
General Mills, Inc.	140.6		516.1	
Pillsbury Mills, Inc.	82.5		331.0	
Total		223.1		847.1
Percent of group		(.8)		(2.1)
Proprietary drug:				
American Home Products Corp.	93.2		234.5	
Sterling Drug, Inc.	86.3		166.9	
Vick Chemical Co.	38.0		72.7	
Total		217.5		474.1
Percent of group		(.8)		(1.2)
Corn products:				
Corn Products Refining Co.	155.6		290.2	
Penick & Ford, Ltd., Inc.	18.7		52.5	
Total		174.3		342.7
Percent of group		(.7)		(.8)
Group total		26,707.0		40,498.7

Senator KEFAUVER. You are an economist, aren't you?

Dr. THOMSEN. Yes, I am.

Senator KEFAUVER. Don't you have faith in the Federal Trade Commission? You are very familiar with the Fortune people, aren't you? Why didn't you accept their figures?

Dr. THOMSEN. Because this was available and represented that particular period of time.

Senator KEFAUVER. It showed for the three companies a lower profit than the Federal Trade Commission showed.

Dr. THOMSEN. No; that was not the reason.

Senator KEFAUVER. It did show a lower profit. You don't think that entered into your calculations?

Dr. THOMSEN. No.

Senator KEFAUVER. Would you take what you say is not a formal report, not a formal finding—which you have described this as being—and as an economist would you put it up against a carefully documented Federal Trade Commission finding, and the finding of the Fortune people which has been well considered by economists?

Dr. THOMSEN. What year or years was the Fortune magazine, the data that you say are superior?

Senator KEFAUVER. 1958 is the date.

Dr. THOMSEN. That 1958 is not a representative year. That was the year in which profits were higher.

Senator KEFAUVER. That was the year of depression in a great many industries.

Dr. THOMSEN. In a great many industries, but it was a year of unusually high profits in the drug industry, Senator.

Senator KEFAUVER. We had the Federal Trade Commission, I believe——

Dr. THOMSEN. What year was the Federal Trade Commission?

Senator KEFAUVER. We had it over a period of 10 years from 1949, the third quarter.

Dr. THOMSEN. 1956, 1957, 1958, and 1959 were high years. I have in my analysis that I submitted——

Senator KEFAUVER. You say that 1958 and 1959 are high profit years?

Dr. THOMSEN. Higher, yes; they are higher years.

Senator KEFAUVER. Let's look at one of these tables you are showing us. You show the profits going down in those years. You had the profits going down, didn't you?

Dr. THOMSEN. May I just comment?

Senator KEFAUVER. Now you say that the profits went up during these years.

Dr. THOMSEN. I say that 1958 was a relatively high year on profits.

Senator KEFAUVER. Here you have it, in the trend of drug prices, 1947–58. You have profits going down in 1957, so what do you mean by telling us that they were going up?

Dr. THOMSEN. I say they were high in 1958, that 1958 is not a representative year.

Senator KEFAUVER. You said that——

Dr. THOMSEN. The chart that Dr. Smith presented shows that 1958 was a high year, except for a few years here, and the prewar years, this is a high year. It is not a representative year. In my own state-

ment I have a brief reference to changes in profits which occurred, and you can see from that that it is a high year, an unrepresentative year.

Now Mr. Cottle used all companies available, Senator, for a period of several years, and I say that that is more representative than to pick out one year which is a high year and to call that representative of the variations among those industries.

Senator KEFAUVER. Dr. Thomsen, we took a 10-year period in our chart. You say profits went up in 1958 but according to your chart here, profits went down. Now you say that that is a high year and is unrepresentative. They are going higher in 1959, aren't they?

Dr. THOMSEN. The study of Woodward and Adams, which has been submitted to you, of 10 companies shows profit margins for each of the years 1947 to 1958. They varied substantially throughout that period of time. The study shows a variation in profit margins from 9.4 percent in 1953 to 15.7 in 1948. The year 1958 was one of the higher ones, and hence is not representative. Profit margins declined from 1957 to 1958, and again from 1958 to 1959. But in all those years, and in all these years they all were significantly lower than for the years 1947 through 1950 and the prewar years. But they were high, and they are not representative of recent years.

Senator KEFAUVER. According to your chart here, you have 1956 high, 1957 high, and 1958 high. We know that 1959 is going to be high. So what is representative?

Dr. THOMSEN. I don't believe that anyone looking at that chart would say that 1958 is representative. I believe it—I leave it to anyone's judgment to look at it as to whether it is representative.

Senator KEFAUVER. I notice on this chart that we have been looking at, it refers to PMA staff computations on rate of return on total capital. Is that your own calculation?

Dr. THOMSEN. No, as I indicated just a few minutes ago, that is from a study by Woodward and Adams of 10 companies, and it is reported in the study which was turned over to you I believe this morning or was it yesterday?

Dr. SMITH. Yesterday.

Dr. THOMSEN. Yesterday, a 10-company compilation. To me, Senator, if you will pardon me for saying so, it seems that by picking out 1958 and saying that that is because it is a more recent year is not trying to get at the facts as to what is representative, because it is obviously not a representative year, even though it is more recent. It is a high year, profits were higher in that year.

Senator KEFAUVER. Dr. Thomsen, even according to your own chart here, for the last 4 years the figure has been about 20 percent after taxes for each year. Look at it. It has been about 20 percent after taxes, now.

Dr. THOMSEN. In 1956 and 1957 and 1958, near that in 1958.

Senator KEFAUVER. It was near that in 1958 and it has gone up some in 1959.

Dr. THOMSEN. But it was not that in 1955 or in 1954, or 1953 or 1952 or 1951.

Senator KEFAUVER. It was up above 25 back in 1947. But anyway, in the last 4 years, it has been about 20 percent, according to your chart, after taxes?

Dr. THOMSEN. Yes, I believe that any statistician who didn't know the industry you were talking about just looking at the figures there would say that there was a trend, that he might compute a trend and it would have a downward slope there, and 1958 would be above that downward sloping trend line, and that 1958 would not be representative of the period.

Senator KEFAUVER. Dr. Thomsen, does this represent ethical drugs that you have at about 20 percent?

Dr. THOMSEN. Yes, sir, and that is all reported and described fully and the firms included, everything about it is fully described in the study by Woodward and Adams.

Senator KEFAUVER. This represents the profit trend on ethical drugs in the last few years, is that correct?

Dr. THOMSEN. The Woodward and Adams study of 10 companies.

Senator KEFAUVER. You have comparative industry earnings 1953–57, ethical drugs, 10 to 15 percent. You show yourself that they are very much above that. Does that include these 3 companies you are talking about?

Dr. THOMSEN. Would you mind repeating the question, please?

Senator KEFAUVER. I say at one point you have the profits up about 20 percent in the last 4 years.

Dr. THOMSEN. These are two different things. These are profit margins in these charts that you are referring to now. This is rate of return on total capital, this chart that I am referring to here. That is rate of return on total capital.

Senator KEFAUVER. What is total capital, sir?

Mr. THOMSEN. That is the total capital invested in the business, used in the business. That is the total amount which would include all of the investment in physical properties, in the properties used in the industry.

Senator KEFAUVER. Then you figure that amount of the Federal Trade Commission about the same as net worth?

Dr. THOMSEN. And the other chart that you refer to or rather——

Senator KEFAUVER. Just a minute, is that the same as net worth?

Dr. THOMSEN. No, sir, it is not.

Senator KEFAUVER. What is the difference? Total assets? Total investment?

Dr. THOMSEN. No, total capital is the total amount of capital used in the business. Now a part of that is borrowed capital, which may be obtained by floating a bond, a corporation bond, and the net worth is after debts.

In other words, it is total capital, in effect it is total capital minus debt.

Senator KEFAUVER. Whether you take total capital or whether you take what you have here, or whether you take net worth or whether you take investment——

Dr. THOMSEN. You will get a different figure depending on what you take.

Senator KEFAUVER. Yours is a little lower than the Federal Trade Commission and Fortune figures. But in any event, you have it in the last 4 years up about 20 percent after taxes. That, of course, means 41 or 42 percent before taxes; isn't that correct?

Dr. THOMSEN. On the Woodward and Adams report on page 19 it shows the rate of return on the common stock equity on the total capital, so that you can get it either way. But the middle column there in the Woodward and Adams study, I have it marked here if I find it, there are so many data, Senator, used in connection with these studies that you have to go through them and locate them before you can talk intelligently about them.

The rate of return is found on page 19. The profit margin is in the middle column, column C, the rate of return on capital is the first column on page 19.

Senator KEFAUVER. What is this you are talking about?

Dr. THOMSEN. This is the Woodward and Adams study that has been turned over to you.

Senator KEFAUVER. Is that in one of the documents that has been filed with us?

Mr. CHUMBRIS. No. 3, Senator.

Senator KEFAUVER. How many companies does this include?

Dr. THOMSEN. Ten companies, and the chart that you have here, Senator, that you were referring to is the rate of return on total capital shown there in the left hand one of the three columns under total capital.

Senator KEFAUVER. This does not include some of the most profitable companies such as Schering, Carter, and American Home?

Dr. THOMSEN. It includes all of the companies for which published data in Moody's Industrial Manual were available, Senator, all of the companies that we could find there, in any event, that Woodward and Adams could find.

They searched the records for all of the companies for which published data were available and they were included.

Senator KEFAUVER. Published data is available for all of these companies.

Dr. THOMSEN. What is that?

Senator KEFAUVER. For the companies I have mentioned published data is available.

Dr. THOMSEN. Not covering all of these items that they were studying.

Mr. CHUMBRIS. It covers three of the six companies.

Dr. THOMSEN. Did you say American Home Products? That is a large company including a complex of many things. In that no company in which the ethical drug operations could not be separated out were not used because they wouldn't mean anything. In the case of American Cyanamid, for example, as I understand it they don't publish special separate figures for Lederle and therefore you can't use them because it wouldn't mean anything.

And I did not make this study. Woodward & Adams made it. But my understanding is I have been assured by one of the authors that all of the companies for which published data were available and which were pertinent, American Cyanamid, for example, were included.

Senator KEFAUVER. Schering's data has been available; they made substantial profits. But you have the rate of return on common stock equity in 1958 as 19.3 percent after taxes. I think our figure for 1937 was 22 percent. This is just a little lower than the Federal Trade Commission figures.

Dr. THOMSEN. Yes; this chart that you have here in the Woodward and Adams study is this column right here.

Mr. CHUMBRIS. Dr. Thomsen, your thesis in the document that you furnished the subcommittee is that neither net worth nor total capital is the proper basis for the purpose of this subcommittee's investigation.

Dr. THOMSEN. Yes; I think it is quite obvious that it is in it.

Mr. CHUMBRIS. You state that in page 17, is that correct?

Dr. THOMSEN. Yes; for the reasons I gave in my statement, I am sure that neither profits per dollar of net worth or total capital as far as that is concerned or the ranking of different industries with respect to profit margins have any relation or significance in connection with how much you can reduce drug prices by reducing or eliminating profits.

Senator KEFAUVER. I have read your statement but it would seem to me just offhand that if companies charge twice as much as the industry average, it would have an effect on prices.

Dr. THOMSEN. No, sir; if you have the ranking of the drug industry among all other industries, you know whether it is the fourth in line or third, it doesn't tell you one single solitary thing as to how much you might be able to reduce prices by reducing or eliminating profits.

And if you have a figure on profit per dollar of net worth, it doesn't tell you one single solitary thing about it for the reasons that I have in my statement, and I am sure that any economist anywhere in the United States of America who is an economist would agree with that, if you will read my reasons and look at my statement.

Senator KEFAUVER. I don't want to burden you with this, but the drug industry is twice the average of the manufacturing industries in profit on net worth or investment.

Dr. THOMSEN. And that doesn't tell you one thing, sir.

Senator KEFAUVER Just one minute. The drug industry is more than twice the average of the manufacturing industries on sales. I would be awfully hard to convince that you could not reduce the price of these drugs, because you should be satisfied with an average profit.

Dr. THOMSEN. Senator, I believe you might not be so hard to convince if you read my statement, because the logic is irrefutable. I defy anybody anywhere to refute it. Profits per dollar of net worth do not mean one single solitary thing with reference to how much you can reduce drug prices. It doesn't tell you one thing. You could have all the figures on profits per dollar of net worth that you could collect on all the industries in the world, and still you would not know one single thing with or about it if you just have profits per dollar of net worth for the reasons that I have indicated in my paper.

Senator KEFAUVER. It would certainly seem that if instead of making 22 percent profit, which would be about 45 percent before taxes, the drug companies would be satisfied with 11 percent as other manufacturers are, and there would be considerable money available for some purpose.

Dr. THOMSEN. No, sir.

Senator KEFAUVER. Whether it could be used for the reduction of prices, I don't know. But let's take sales, which is 27 percent before taxes and 13.1 percent afterward for 20 companies. Take one-half of that 13 percent and you would still be above the average manufacturer; that would be 6.5 percent by which you could reduce your prices.

Dr. SMITH. May I ask——

Senator KEFAUVER. Just a minute. I am talking to Dr. Thomsen. Is that not true?

Dr. THOMSEN. I would say that it doesn't give you any indication, Senator, because you don't know what it means.

In other words, you might have an industry, for example, meatpacking, which has a profit margin per dollar of sales of 0.6. But it has a tremendous turnover. The kind of commodity that they handle means millions of dollars a day turnover. Now with a small amount per dollar of sales like that, less than 1 percent, you can still have a very large profit on net worth you see, and the profit per dollar of net worth does not tell you anything, and I mean "anything." It tells you nothing whatsoever about what the profit, the absolute profit per dollar of sales is, and that is the only thing that will tell you how much you might reduce drug prices.

Senator KEFAUVER. That is the reason I pointed out both of them. We are talking about sales now. You are twice above the average manufacturing industry in both of them.

Dr. THOMSEN. Again Senator, I say that——

Senator KEFAUVER. If you would be willing to reduce your net profit on sales from 13.1 percent after taxes down to even half that, 6.5 percent—which would still be larger than the average manufacturing industry—that would, of course, give you room to reduce your prices, wouldn't it?

Dr. THOMSEN. You say if you reduced them by 6 percent?

Senator KEFAUVER. Yes; 6 percent.

Dr. THOMSEN. You say if you reduced the drug company profits by 6 percent?

Senator KEFAUVER. On sales.

Dr. THOMSEN. Now the drugs when they leave the manufacturer's hands, they go through successive markups, which means, and I think nobody would want to dispute those figures, that when they reach the consumer, they have doubled in price at least. So your 6 cents would be 3 cents. So in other words if your profit figure of 13.1 were representative, which it is not, because it is for a high year, but if it were, and you are going to cut them in half, by the time that reached the consumer that would be 3 cents, and I submit that what has been discussed here and the data that has been put out and featured by the press is not talking about reducing drug prices in terms of a few pennies, 2 or 3 pennies per dollar paid by the consumer for drugs, but in terms of hundreds and thousands of percents, really ridiculous figures of that sort that have no relation to reality at all.

I say that using your own figures that you just now gave me, that is the 6-percent reduction in the profit margin of the drug manufacturers would mean only 3 cents to the consumer.

Senator KEFAUVER. That would be about 27 percent and if you reduce that by half, that would be 13 percent reduction in the price.

Dr. THOMSEN. No, sir.

Senator KEFAUVER. Off the retail price.

Dr. THOMSEN. You are not using profits per dollar of net worth as equivalent to the profit margin?

Senator KEFAUVER. No; I am using profits on sales.

Dr. THOMSEN. Your own figure, which I consider as being unrepresentative because it is for 1958, is 13.1. Well, if you take one-half of that and say we cut the profits in half, that would then be approximately 6.5 cents, you see.

Senator KEFAUVER. Then you see that would cut taxes in half too, so you wouldn't have to pay 13 percent in taxes. You would pay less in taxes.

Dr. THOMSEN. We will modify it, but even then it still doesn't make any difference because you just tell me, give me any figure that you are going to reduce it you see, and we will cut that in half.

Senator KEFAUVER. According to yours——

Dr. THOMSEN. We will cut it in half because of the markups. You have to cut that in half, and it means just a few pennies anyway you cut it. You can cut your cake this way or that way or the other way and it all comes out a few pennies per dollar of drug prices paid by consumers.

Senator KEFAUVER. If the markup is going to increase the prices regardless of what the manufacturer's price is, then you might as well increase the manufacturers' price to any amount.

Dr. THOMSEN. It still wouldn't make any difference even if you make allowance for the difference in the markup. As a matter of fact I think that anyone who knows merchandising or merchandising of drugs or any other products will admit that a few cents change per dollar on prices would hardly be noticed in the marketing system. In other words, retailers probably would pay no attention to such a small change and they would go on charging the same price. I don't think it would have any effect. I honestly believe, and I believe that the materials that I have in my study will bear me out, that to reduce profits of drug manufacturers by one-half would have no appreciable effect at all on retail drug prices.

Senator KEFAUVER. Ethical drugs is a $2.5 billion a year business. If you can reduce your net, half of 13 percent which would be half in taxes, that would be about 13 percent of $2.5 billion, which would be a tremendous saving to the American consumer who must have these drugs.

I don't think the wholesalers and retailers are going to take advantage of the situation and just mark up regardless of what the price is. I know they won't, but it would make a half billion dollar difference in the retail prices to the people who have to have these drugs.

Dr. SMITH. It seems to me that there are several things being discussed here at one time and it is only leading to confusion and I wonder if I could ask, for my own clarification, a question. May I ask why it is that there is frequent reference to the drug industry being the highest profit industry in terms of net profit to sales and the figure mentioned, if I remember correctly, is something around 22 percent. Where does that figure come from?

Senator KEFAUVER. 22 percent is on net worth after taxes. The figure on sales is somewhat lower, about 13 percent, but that is still the highest of all industries.

Dr. SMITH. I am sorry but I must disagree, and there are several reports which would support my statement. For example, I have in front of me a statement from the First National City Bank of New York which puts drugs down considerably in the list, and the same is true of another survey that I have from News Front. It seems to me that perhaps there is substance to what Dr. Thomsen says that these figures may be of greater interest to bankers than they are actually to the health of the people.

Dr. THOMSEN. They mean nothing, sir.

Senator KEFAUVER. We are talking about manufacturing corporations. We have had all the high-profit corporations listed on our tables and all the records we have show that among manufacturing companies by industries, drug manufacturing companies have the highest profit on net worth and the highest profit on sales.

Dr. SMITH. Those figures don't agree with ours.

Senator KEFAUVER. Let's see what your figure is then. What do you have?

Dr. SMITH. Here, for example, the First National City Bank shows profit in cents per sales dollar for drugs 11.4, and that is considerably lower than several others which are mentioned here. Then News Front shows drugs down at 10.6 and there are quite a few ahead of this, including banks, for example, which run around 21 percent, commercial banks.

Senator KEFAUVER. Banks are not manufacturing industries.

Dr. THOMSEN. Senator, if you will give me 2 or 3 minutes.

Senator KEFAUVER. They are controlled by the Government and I think the Government allows them to make too much money; I will say that.

What manufacturing industries do you have there which are higher than drugs?

Dr. SMITH. Cement—I will read the list here from the First National City Bank.

Mining and quarrying as opposed to metal and coal mining comes first, then there is cement. Telephone and telegraph, electric power and gas, et cetera. In this other one, News Front, we have cement, personal and business credit institutions, commercial banks, water supply companies, communications, utilities, used petroleum and natural gas.

Senator KEFAUVER. We have already discussed that chart, I believe. I think that is the same chart that was put in by Ciba.

Mr. CHUMBRIS. Mr. Chairman, may I suggest——

Senator KEFAUVER. Let's get this straight while we are at it. We pointed out, sir, that utilities are regulated by either the U.S. Government or by State governments. They are generally allowed to make 6 percent on investment. In order to make their 6 percent on investment, the States and the Federal Government allow them rates which do give them a higher profit on sales. They have very high investment. The same is true of banks. On the chart that you show here, you do have cement for the year 1958 at 16.1 percent. Among manufacturing companies, drugs are listed at 11.4 percent.

Dr. THOMSEN. Senator, could I ask you a question?

Senator KEFAUVER. In terms of net worth, I think we had drugs above cement at the time Ciba testified. It should be kept in mind that the Federal Trade Commission has been proceeding against some cement companies for a considerable period of time.

The figures show, I believe, that after taxes in 1957, 12 cement companies had net profits after taxes on net worth of 14.2 percent; 21.4 percent, I believe, was the Federal Trade Commission figure for drugs during that same year.

On the second figure you quoted, Dr. Smith, the 10.6 percent industry average, is that chemicals and drugs together? It says chemical-drugs and American Home is listed and so forth.

Dr. SMITH. You will find on the opposite page chemicals separated from that. This presumably refers to drugs or that part of the drug industry from which they can extract figures.

Senator KEFAUVER. It may be according to this chart that cement for 1 year was ahead of drugs in profits after sales, not on net worth. The Federal Trade Commission figures are different, but in any event, with the possible exception of this year for cement, in manufacturing industries drugs were the highest.

Dr. SMITH. I am afraid that I must disagree with those figures, and I think that in view of that, Mr. Senator, that this is a subject that deserves considerable exploration before we can make a flat statement. I would be surprised, for example, if some of these statements coming out from reputable sources were found to be without basis, and yet there seems to be conflict.

Senator KEFAUVER. Coming from reputable sources and without basis—what do you mean?

Dr. SMITH. For example such as those coming from banking institutions, from investment houses, from analytical journals.

Senator KEFAUVER. We have used for profit figures the Federal Trade Commission and Fortune magazine, which includes, I think, about the best recognized data that you can get.

Senator HRUSKA. Mr. Chairman, may I inquire on what basis the Federal Trade Commission computations are made?

Senator KEFAUVER. The Federal Trade Commission makes an annual calculation of profits.

Senator HRUSKA. On what basis, net worth on sales?

Senator KEFAUVER. On net worth and on sales.

Senator HRUSKA. That is the net worth to which you have referred?

Senator KEFAUVER. Net worth after taxes for the year 1957 was 21.4 percent.

Senator HRUSKA. Mr. Chairman, it happens I have read Dr. Thomsen's statement, and I find it very interesting. Several times, if the Senator will yield, the witness has made the statement that net worth does not tell you one single thing about this whole thing, and I would like to refer and question the witness with regard to the material contained in his statement commencing at page 13.

I think he makes an irrefutable case that he is correct in his statement that net worth does not tell anything, and if he takes it step by step, any reasonable and fair minded person will follow to that conclusion.

I don't think it will take more than 2 or 3 of these pages to show that by the examples that he has given. Mr. Thomsen, may I suggest that you take page 14, the illustration there, and give us a rundown of that and an explanation of it to show what you have said by way of a conclusion?

Dr. THOMSEN. Yes, sir, I would be glad to do so.

When I see data such as those that have been introduced throughout these hearings on profits as a percentage of either invested capital or net worth, it seems to me that the only result of the parading of those data in the committee hearings and out in the press is to mislead and confuse rather than to enlighten, and I would like to show you just exactly why that is so.

All of this discussion that we have been having here just recently about these various matters is completely beside the point.

Let's take a very extreme example outside of the manufacturing indutry. Let's take a hardware store with an investment of $150,000 and a law firm with an investment in books and so on of $12,000.

Senator HRUSKA. You are reading now from page 13, sir.

Dr. THOMSEN. Page 13, the last paragraph. Each grossing $600,000 per year with a profit of $30,000 or 5 percent of sales in each case. Expressed as percentage of investment, this would be 20 percent for the hardware store and 250 percent for the law firm. The comparison obviously is meaningless. Some businesses require a large inventory of fixed assets such as land, buildings, and equipment, or raw materials and finished or purchased products, or both.

Other businesses have very little money tied up in such physical properties.

Profits as a percentage of investment are simply figures without meaning except for certain very limited purposes that are not included among those for which they have been used.

Let us look at two more illustrations. Let us take the case of two firms, A and B, not necessarily in the same business, for which we may be trying to judge the reasonableness of profits made.

Firm A has an investment of $500,000, firm B, $50,000. They both have sales of $2 million. The profit margin as a percent of sales for firm A is 2.5, for the other firm it is 0.5. Their profits after taxes are $50,000 for firm A and $10,000 for B, and the percent of investment, the profits for firm A are 10 and for firm B, 20. So in other words firm B there has twice as high a profit per dollar of investment and the same thing would be true presumably for net worth.

But it is only one-fifth as high in profits per dollar of sales you see. And you see when you have the profits per dollar of net worth, it doesn't tell us anything for that reason, unless you know what the turnover of capital is.

On page 15 I have a table which is a better example of that.

Senator HRUSKA. The narrative explanation is on page 16 is that not correct?

Dr. THOMSEN. Yes, but I will explain it without reading my explanation there. Store A owns the building and has $100,000 mortgage, its net investment the building is worth $180,000 so it has an investment of $80,000. Store B owns the building outright, no debt, and a value of $180,000. Store C rents a similar building and doesn't have any investment.

So they each have a stock of goods of $50,000 and their total capital invested is $230,000 for stores A and B and $50,000 for store C. The net worth is $130,000 for Store A because of the mortgage that they have. For Store B it is $230,000 and for Store C $50,000.

Now annual sales are exactly the same, $900,000. They sell exactly the same products and at exactly the same prices and have exactly the same annual sales. Store A has interest on the mortgage $5,000. The cost of building maintenance, insurance and upkeep, painting and so on for stores A and B both are $9,000, but Store C, which rents, doesn't pay any of that. The landlord pays it. The annual rent is nothing for store A and store B but is $18,000 for store C. Other operating expenses, that is the cost of clerical hire and cash registers, heat, light and so on are $837 for each one, so in other words they are selling the same merchandise at the same prices and they have exactly the same expenses except for the differences in the minor item of rent.

Now there, their total annual expenses then if you will add those up, you will find for store A, $851,000, store B, $846,000, store C $855,000, giving a net profit after taxes of $49,000 for store A, $54,000 for store B and $45,000 for store C.

Now then, their net profit as a percentage of sales, which you get merely by dividing, is 5.4 for store A, 6.0 for store B and 5 for store C. The net profit as a percent of total capital is 21.3 for store A, 23.5 for store B, and 90 percent for store C. And net profit as a percent of net worth is 37.7 for store A, 23.5 for store B, and 90 for store C. So in other words, here are 3 stores operating exactly the same way with the same merchandise selling in the same quantities at the same prices with all their expenses exactly the same except for rent coming out with one store having a net profit per dollar of net worth 4 times approximately higher than another store. It shows—the illustration speaks for itself—how utterly ridiculous it is to try to form any conclusion whatsoever regarding what might be done about lowering prices by looking at profits per dollar of net worth. It is child's play. It doesn't mean a single solitary thing.

I assure you, Senator, I am positive any other economist in the whole United States of America will agree with me on that.

Senator HRUSKA. Now, Mr. Thomsen, there are three of those stores there; if we took the bottom line of page 15, net profit as a percent of net worth, added up those figures 37.7, 23.5 and 90, and divided 1 by 3 roughly it would come out at 50 percent, wouldn't it?

Dr. THOMSEN. Yes.

Senator HRUSKA. So we have an average of 50 percent of net profit as against net worth. Yet that ranges all the way from 23.5 percent to 90 percent.

Dr. THOMSEN. Yes.

Senator HRUSKA. So 50 percent is not very disclosing or revealing, is it?

Dr. THOMSEN. No. If these were industries instead of averages you would say here is one that is 90 instead of 50 or whatever the average actually is. I haven't averaged them.

You say that is terrible, way up high there, way above the average, and yet it is not charging any more. Its prices are just the same and it is selling the same merchandise.

Senator HRUSKA. I think that is a tremendously lucid explanation of it. Now let's turn to page 21.

Senator KEFAUVER. Just before he leaves there, I don't believe that I have heard testimony from drug companies that they rent their plants. They are not in the situation of store C.

Dr. THOMSEN. That has nothing to do with it, Senator. That is a matter of principle. I could use any other kind of expense.

Senator KEFAUVER. I think also the instance where the landlord gets $18,000 in rent, he wouldn't let that be $18,000 very long. Store B which owns the building doesn't have to bother with the landlord. I can only say that I think you have to consider profit on net worth and also profit on sales and figure them together but I might ask you in passing why is it that all regulatory agencies, such as the Federal Power Commission and the State regulatory agencies, figure investment as their basis of determination of the proper rate of return which is just about the same as net worth?

Dr. THOMSEN. Well, sir, I would be happy to answer that. They do that and they say "We are going to allow you so much in the way of profit on your investment or on your net worth," whatever they happen to use. All right, then they say "You reduce your prices or we will allow you to raise your prices," which is generally what happens in cases of that sort.

"We will allow you to raise your prices so that you will make this much."

Now you can make estimates from that for that one company you see by going back to their profit margin as to how much of a raise you can stand in order to take that. But you have to translate it over into the profit margin. And you might just as well start with that.

In other words, your figures that you have here, and which are germane to the question of what you might do about drug prices in relation to profits are the absolute figures per dollar of profit margins, per dollar of sales. If this were the correct one, why then I would be happy to discuss how much you might reduce drug prices by reducing this profit any given amount.

Or if you take another figure, 12.5, that would be different. But that is the only thing that means anything.

Senator KEFAUVER. I just wanted to bring out that, in any event, the regulatory agencies do feel that rate of return on investment and net worth is not meaningless.

Dr. THOMSEN. But, Senator, they don't mean that it tells them how much they can reduce prices. The rate of return to which they are going to limit them, they can only determine that by going to the profit margin as to what effect that will have on prices. So what you say doesn't vitiate in any way what I have said.

Senator KEFAUVER. What I mean is they allow prices to go up and down relative to the 6 percent return on investment. So it is not meaningless.

Dr. THOMSEN. Yes, by itself it is. In other words, let's say that a public utility regulatory body finds that you are making 10 percent, and they want to allow 6 percent. So in other words, they want to take off 4 percent of your profits per dollars invested or per dollar of net worth. How much would they have to reduce rates in order

to do that? They would have no more idea than you would on drug prices here you see. They would have to go over to the absolute profit margin on that in order to determine that.

And they would have absolutely no idea whatsoever as to how much they would have to have prices in that industry reduced in order to bring the rate of return down to 6 percent.

Senator KEFAUVER. We are not talking about regulating prices. I just point out that the U.S. Government and the State agencies feel that the profit on investment or net worth in the case of utilities is the fairest basis on which to regulate rates.

Dr. THOMSEN. Only for determining at what level they want to hold them to, but that is on profits but it doesn't tell them anything whatsoever now and they wouldn't have any more idea than the man in the moon how much they should reduce prices to do that unless they go to the profit margin.

In other words, the profit per dollar of net worth doesn't tell them one single solitary thing about how they should regulate the price.

Senator KEFAUVER. That is a matter of mechanics in figuring out the rate that will reduce this percentage of return on investment.

But anyway you go ahead.

Dr. THOMSEN. It is a matter of mechanics in this case too. In other words we believe if the profits per dollar of net worth or capital invested are higher or higher than we think it ought to be, you say we think this industry ought not to be making that much so we are going to force them to reduce prices.

Well, how much? You still wouldn't have any idea. With a 20 percent per dollar of net worth or with a 40 percent or 60 percent or 10 percent or 5 percent, the profits per dollar of sales, the profit margin might be 0.5 or 2.5 or 5 or 10 or 20 or 50. It doesn't tell you anything.

Senator KEFAUVER. We get your point.

Senator HRUSKA. Referring Mr. Thomsen, to table 2, can you comment as to its significance there as to the unadjusted basis as to the net profit margin and the adjusted basis?

Dr. THOMSEN. Yes, the unadjusted are the figures reported by Cottle & Whitman for these various industries. Now there are a number of factors which are responsible for variations among industries in the profit margin. I have listed those under four categories, which I believe encompass everything that you can possibly think of.

One is turnover, others degree of risk, the other is other internal conditions affecting profits in the industry, and the fourth is external conditions such as the general business cycle. I have used this analysis, because of a time limitation only one factor, turnover. The reason I was able to use that is because Cottle and Whitman, which I think is a very useful document there, had rates of turnover for the same industries, which were comparable you see. And I made an adjustment based on a regression line of those data of the original data, and it came up with the figures in the second column, which shows that when you allow for the rate of turnover just one of the four factors that I mentioned, when you allow for that one factor, you explain over half of the variation existing among these industries in the original data.

Now I would like to say this, that I have done this merely to show that there are rational explanations of these variations among industries including the ethical drug industry in the ranking and profit margin. But I would like to say this: That that doesn't mean any more, this ranking of industries by profit margins, that is profit per dollar of sales, any more than it does in regard to profit per dollar of net worth. It is just like this. You can go from one to the other by taking the capital turnover and the process is like a dog chasing his own tail.

The dog isn't getting anywhere and the committee isn't getting anywhere either by using figures of that kind.

Senator HRUSKA. However, Mr. Thomsen, in the computation which you have made from the unadjusted to the adjusted basis allowing for capital turnover to which you refer, item No. 3 there on page 21 of your statement indicates that there would be a difference between those two bases in ethical drugs from 10.1 to 7.5 percent.

Dr. THOMSEN. Yes, sir.

Senator HRUSKA. Whereas at the bottom of the page in grocery chainstores, where presumably the turnover is much greater, and meatpacking, we find the exact opposite to be true, isn't that the fact? In grocery chainstores the unadjusted basis is 1.0 percent, the adjusted basis allowing for turnover is 6.5 times as much, namely 6.5 percent.

Dr. THOMSEN. Yes, sir.

Senator HRUSKA. And in meatpacking it is 0.6 percent, with over 9 times as much for the adjusted basis, namely 5.5 percent.

Isn't that what you sought to illustrate by this example?

Dr. THOMSEN. Yes, it is, and it just shows that by taking just one factor affecting profit variations by industries into account, you explain a large part. You bring them all together a whole lot more than they were at the start. If we had quantitative measures of some of these other factors, which we could get by searching long enough and had time, we could come up with an even closer adjustment than that you see.

But as I say, even then, even when you do that, the ranking of industries by profit margins means no more than profit margins net worth.

The only thing that means a darn thing, that means anything at all in relation to how much you can reduce drug prices I repeat is the absolute profit margin. And you can formulate very definite positive conclusions regarding how much drug prices can be reduced by reference to that absolute profit margin, and that is the only way.

Senator HRUSKA. Mr. Thomsen, could that be done as an industry or would you have to go to each individual company for that, to analyze the basis of profit and the amount of absolute profit and to make a proper adjustment in the excess profit or the lack of profit therein?

Dr. THOMSEN. Of course, there isn't any way as far as I can see to do it. I mean it is all an academic exercise you see as to what you could do.

Senator HRUSKA. I am trying to fasten it down as to one particular company.

Dr. THOMSEN. Yes, or the industry. You could say here that you could reduce overall drug prices to the consumer if you wanted to cut profits in half, if there were any means of doing so, and still retain our competitive system, if we wanted to go to some Russian system and cut the profits in half, it would amount to a saving to the consumers of maybe 3 or 4 cents, you see.

Senator HRUSKA. For an item?

Dr. THOMSEN. Per dollar.

That cost a dollar, yes; if the item cost 50 cents it would be a cent and half, you see. And I have stated before that I believe in most cases that would be lost in the shuffle, that the retailer wouldn't even adjust his price for such a small change in the wholesale price. I believe that that could be substantiated.

In other words, for the ordinary drug consumer it would not be enough to pay for his daily newspaper and he probably wouldn't even feel it and I am sure it would never be noticed. If right today they cut all the profits of the drug industry out and the drug manufacturers reduced their prices accordingly, by the time that was passed on to the consumer, I honestly do not believe that more than 1 percent or 2 percent of all the drug users or buyers in this country would ever have noticed or known that any such thing went on.

Mr. DIXON. Mr. Chairman, may I address myself to that point?

A while ago Mr. Thomsen asked you to suggest to him some way that a price reduction could get to the consumer, Mr. Thomsen, I address myself to that request that you made.

Let's take a pill that is made by a given manufacturer and let's talk about it, not in piddling sums but in millions of pills. Now, that pill is being sold to the retail druggist at 18 cents. The druggist must maintain the margin that is necessary for him to stay in business, because he doesn't sell a million pills, he sells small quantities of pills; it is the manufacturer who sells them in millions of units.

Let's assume that that price from the manufacturer to the druggist could be reduced from 18 cents to 15 cents, still maintaining the same margin that the druggist customarily maintains of a 66⅔ percent markup over cost. That 66⅔ percent markup on 18 cents means 30 cents to the public. The 66⅔ percent markup on 15 cents means a 25-cent cost to the public. When a drug is sold in millions of items, I challenge you to say that that would not mean a considerable saving to the public.

Dr. SMITH. I would like to accept that challenge.

Dr. THOMSEN. I would too.

Mr. DIXON. Explain it then.

Dr. SMITH. I would like to speak to it as a physician now and I want to speak to it because I have watched drug therapy for a good many years. You forget just one thing. You are talking about millions of pills, but a patient does not take millions of pills. He takes a few during the course of an illness, so how many pennies will he save?

Mr. DIXON. But you have got to think about the whole public.

Dr. SMITH. I am thinking about the whole public.

Mr. DIXON. Don't you think that 10 cents is a considerable difference to the purchaser who takes a pill?

Dr. SMITH. Not to the individual.

Mr. DIXON. A 5-cent saving on 30 cents is more than one-sixth of the cost. That is a savings, in my way of thinking, yet you say it is nothing.

Dr. THOMSEN. Sir, may I answer that? I could fix up some other ridiculous example. You have taken 3 cents on 18 cents. How much is that per dollar of sales, per dollar? About 15 percent. In other words, over 15 percent.

Mr. DIXON. You asked me to propose an example to you. Do you have a chart in front of you?

(The chart referred to, Exhibit No. 160, may be found in part 16, p. 9176.)

Dr. THOMSEN. Yes.

Mr. DIXON. On that chart the sales dollar is broken down for 20 drug companies.

Dr. THOMSEN. Yes.

Mr. DIXON. The selling cost there is 24 cents. I would assume that is a pretty high promotion and selling expense.

Let us assume something would bring about a reduction in expense which normally, with that change in price, would be reflected in a higher profit. I pointed out to you a 3-cent reduction from 18 cents. At the moment I don't know what that really would amount to in percentages.

Dr. THOMSEN. Over 15 percent, wouldn't it?

Mr. DIXON. Yes, over 15 percent.

Dr. THOMSEN. In other words, you are not only going to take all of the profit of the drug companies if this is an average product, and I think we should talk in terms of representative or average product, you are not going to take all of the profit but you are going to push him over into the loss column.

Mr. DIXON. This profit is after taxes, and that would be about 27 percent before taxes, so you are going to do this before you end up with something.

In other words, your taxes would be considerably lower on what you would have to pay.

Senator KEFAUVER. I think it is clear that if profits on sales were reduced some, there would be some reduction that the companies could pass on to the druggist and to the consumer.

Dr. THOMSEN. There would be some but it would just be in terms of a few pennies.

Senator KEFAUVER. You say it might not affect any one particular person very much, but taking the fact that two and a quarter billion dollars of drugs are sold——

Mr. DIXON. Let me give him another example.

Senator KEFAUVER. I think we ought to get on to something else.

Mr. DIXON. I want to give one other example. It has been testified here, Mr. Thomsen, that some of the smaller companies have to meet rigid tests on quality control to be able to sell to the Government. For instance, they sell prednisone or prednisolone to retail druggists at slightly over $2 for a hundred pills, whereas the larger companies charge the druggists $18 for the same quantity of pills. Do you see any savings to the public if the druggist maintains his same margin of a 66⅔ percent markup of $2? How much is that, did you say? That cost to the consumer is about $3.34, isn't it? But maintaining the druggist's same percentage of markup ,when it is applied to an $18

item, that brings the consumer's cost to $30. There is a considerable savings between $3.34 and $30 for the same product, would you agree with that?

Dr. THOMSEN. I don't know anything really about retail markup. I am just not an authority in that field.

Mr. DIXON. You know the difference between $3.34 and $30, don't you?

Dr. THOMSEN. I don't understand your example, and I don't know anything about that retail field. I haven't studied it. I do have the information that the average, on the average it is at least twice as much and that is all I can say about it.

Mr. DIXON. But you said the reduction would be lost in the retail field. But the small companies, when they came here, said they made satisfactory profits and they recited them for us. They appeared to be making satisfactory profits after selling at that lower cost.

The public is not getting these pills made by smaller companies. The public is not getting them because when the doctor writes a prescription, it has on it a trade name of a large company. It doesn't have the trade name of a small company. So the public must pay 30 cents for the pill, not 3½ cents for it.

Dr. SMITH. Mr. Dixon, you are just assuming I think that everything that is sold in generic name is cheaper than the trade name product.

Mr. DIXON. I am not assuming anything, sir. I am reciting to you an example that was given to us here, and I merely took one of those examples.

Senator KEFAUVER. I think that we have pursued this matter far enough. We will have many other things in Dr. Smith's statement to discuss.

Mr. CHUMBRIS. Mr. Chairman, could we just use one illustration on Mr. Dixon's reducing from 18 cents to 15 cents. Senator Hruska and I have been figuring it out here.

Reducing from 18 cents to 15 cents is a reduction of one-sixth of your gross. Now let's take Schering Corp. They have a $75 million gross. They have a $55 million total expense, a $20 million profit and $10 million in income tax.

Now if we reduced everything across the board from 18 cents to 15 cents, the $75 million gross would be reduced to $57 million.

Their expenses of $55 million would practically wipe out their profit.

Dr. THOMSEN. I said the example was simply not realistic and yours shows that.

Mr. DIXON. How do you comment on the example of the small company against the big company?

Senator KEFAUVER. Let's see if we have the right arithmetic on this.

Incidentally I want to put into the record some figures from News Front magazine. Mr. Smith, you said there were a number of manufacturing industries with higher profits than drugs in 1958.

We have copied them all out and we find in that year that cement was the only one that had higher profits on percent of sales.

Dr. SMITH. I didn't say manufacturing industries. I said industries, sir.

Senator KEFAUVER. We are talking about manufacturing industries I have had these copied out, and we will make them a part of the record.

(The document referred to may be found on p. 10997.)

Senator KEFAUVER. Mr. Chumbris?

Mr. CHUMBRIS. Dr. Browne says it should be 62 million instead of 57 million, but you can take it either way. I figured it at 17 million from 75 million. I might be wrong about this.

Senator KEFAUVER. Of course, there is another factor—if you reduced your profits, then you wouldn't have to pay as much taxes, and that item would come down.

Mr. CHUMBRIS. But that 55 million doesn't include your taxes, Senator. That 55 million is a gross expense from the 75 million.

Senator KEFAUVER. In any event, on this table—and I think that it speaks for itself—it is about 27 percent before taxes on sales. If that were reduced to 20 percent before taxes, these companies would still be making a good profit. There would be perhaps not a large reduction in the price to the druggist, but there would be a substantial reduction.

Dr. SMITH. Mr. Chairman, I think some of this discussion is based on the assumption that there are no more diseases to conquer. I believe that if all the diseases in the world were conquered then perhaps we might consider what is too much and too little. But it seems to me as long as there are plenty of diseases to be conquered, there is need for firms and for industries to gain more money so that they can undertake exploration and expansion.

Senator KEFAUVER. I think that is right. Let us discuss research now.

Senator HRUSKA. In that connection, Mr. Chairman, Dr. Smith, isn't it true that the chart which follows page 49, the third chart, tells that story pretty well, doesn't it, in the first part of your statement, part 1?

Dr. SMITH. Yes, Senator.

Senator HRUSKA. Which shows that 44 percent of those profits about which we have been talking after taxes goes back into the business to continue the work which has been done heretofore which has made two things possible heretofore. One to lick those diseases and to cure people, which is the one mentioned, and the other is to make the very profits upon which further work of that kind is possible?

Dr. SMITH. Senator Hruska, there are two or three points that I think are so important when you are dealing with sick people. One is that most of the complaints that I think come from individuals, omitting those who would complain anyway, probably come from the indigent. That person is not medically indigent, he is economically indigent. So let's not forget his whole economic problem, his whole medical care picture, his clothing, his rent, the other things. That is something that cannot be ignored.

Now, when it comes to this question of plowing back a certain amount of money, we can't control the taxes, of course. When it comes to plowing back money, I think those of you who have seen illness in any form probably would be content to permit plowing back any amount that would help us conquer diseases. Earlier today I showed you how many diseases exist. I would just like to mention a couple

of examples to emphasize this point, perhaps three. In my early medical days, I was only briefly exposed to the clinical side of medicine, but it has been my privilege to make ward rounds with a good many people over the years, and I think that any of us who have stood by or watched a person die from some disease that could be controlled by a drug certainly wonder why we can't do more and why we shouldn't be permitted to do more either financially or otherwise.

You see there is one thing that the Uinted States has not yet fully explored, and that is our brainpower and here is an opportunity to explore that to its greatest ability.

I would like to mention, if I could, sir, just a couple of personal experiences because they emphasize this point about which I feel strongly as a physician, and all through this day's hearing I have tried as a physician to look at this problem of the drug industry supplying medical tools.

As a youngster, I lived in Ontario, Canada, and in the Ontario School for the Deaf for a number of years, because my father was associated with it. And I wonder if anybody has lived with several hundred, in this case almost 1,800 boys and girls, ranging from the age of 5 or 6 to 18 or 19 who couldn't speak, who couldn't hear, and could hardly grunt. Most of them were there because of a disease that today we can control with a drug like an antibiotic. Those people were beyond hope of cure; all that could be done was to rehabilitate them so that they could make a living. And I would wonder, also, when we are worrying about whether we are going to save a few pennies on a prescription during a course of a year, which is what it amounts to, how many people have ever been in a mental institution where you find up to 18- or 19-year-old boys and girls, equivalent to young men and women, if they were in normal life, crawling around the floors like animals and when you walk by have them tug on your trouser leg. And I wonder how often people like yourself, could walk through such an institution without saying what is a few pennies if we can get enough money to approach diseases like this?

Those are the challenges that confront the drug industry and the doctors and the pharmacists, and all the other members who make up the health team. And those are the things that they are trying to solve.

Senator KEFAUVER. All right, let's proceed.

Mr. Dixon, do you have some questions?

Mr. DIXON. Yes, Mr. Chairman.

Dr. Smith, without casting any reflection upon the great discoveries that the American pharmaceutical manufacturers have produced for mankind, I still think that we ought to strive here for an objective, factual record. It is for that reason that I go into this question of research, which you raised in your statement.

On page 4 of your statement you said:

The record will show, Mr. Chairman and Senators, that no other American industry has devoted a greater proportion of its resources to provide such great social benefits for the vast majority of our citizens. Let me cite, for instance, a few of the major breakthroughs made in medicine and other medical areas in recent years, breakthroughs that are attributable in some significant way to the laboratories of this industry.

You are talking about the American industry, is that right?

Dr. SMITH. That is right.

Mr. DIXON. You list a number of breakthroughs there. One of them, for instance, on page 5, refers to the development of the antidiabetic sulfonamides. Let's talk about that development. You have stated there that the American industry developed those drugs and that is the way I interpret that language.

Dr. SMITH. That is right.

Mr. DIXON. I understand, on the development of the antidiabetic sulfonamides, that Orinase is the trade name of a generic product called tolbutamide, and that it was developed in the laboratories of Farbwerke Hoechst of Germany. During the examination of sulfa drugs, I understand it was noticed by that company that the blood sugar count was decreased with the administration of the drug and, subsequently, the major breakthrough was made in this German laboratory resulting in a drug to be taken orally for the treatment of diabetes.

Is that true?

Dr. SMITH. Yes, and I see no conflict with my statement, development of the antidiabetic sulfonamides.

Mr. DIXON. You said, sir, the development of the antidiabetic——

Senator HRUSKA. Mr. Chairman, I think counsel ought to be fair with the witness. The counsel ought to read the initial sentence of that whole paragraph.

Senator KEFAUVER. Counsel wants to be fair.

Senator HRUSKA. I am sure he does, but he is pinning the witness down to the words taken out of context inasmuch as he confines them solely to development, whereas if the first words of that sentence in the first three lines are read, it refers to breakthroughs that are attributable in some significant way to the laboratories in this industry. He doesn't say that the laboratories accounted for that development solely and exclusively.

Mr. DIXON. I am going into that.

Senator HRUSKA. I think in all fairness the witness should be given a chance to develop his answer in that context.

Senator KEFAUVER. He will certainly be given a chance.

Mr. DIXON. I certainly don't mean to mislead him, Senator Hruska. What I want to ask him—if he knows—is whether Upjohn purchased Orinase in bulk from the company in Germany.

Dr. SMITH. I don't know the practices of Upjohn or any individual firm.

Mr. DIXON. But your statement implies to me that this product was developed by American industry. I would assume that the word "development," as used here, means that something else has to be done to it, at least after the discovery is made, by American industry before it gets to the consuming public.

Dr. SMITH. I think you are reading into this particular statement "discovery," not "development."

Mr. DIXON. No; I am talking purely about development.

Senator KEFAUVER. It is my understanding that Upjohn has a license to sell this German product.

Mr. DIXON. In the United States?

Senator KEFAUVER. In the United States, and that is where they get the product from; is that correct?

Dr. SMITH. I don't know anything about Upjohn, sir, but I am prepared to stand by this statement as worded.

Mr. DIXON. All right, sir.

Senator HRUSKA. Mr. Chairman, may I inquire——

Senator KEFAUVER. Let Dr. Smith say what it was that in a significant way was developed here.

Dr. SMITH. This group of compounds was made available for the physician in the United States through the efforts of the American industry. That is development and making available.

Mr. DIXON. In other words, you use development in the sense of obtaining a license from a foreign company that has discovered it, developed it, manufactured it in bulk and then sells it over here to this licensee who, in turn, sells it to the American public?

Dr. SMITH. I don't know about Upjohn. I can't tell you about Upjohn. But insofar as obtaining a material, a bulk material is concerned, it is of really not much more importance than finding an idea unless you can make it available.

Senator KEFAUVER. Let's get it clear. Then what was done here is that the drug was made available here although developed and discovered in Germany?

Dr. SMITH. This was tested. The various firms who expressed an interest in this tested it clinically before it could be cleared by the Food and Drug Administration. By "cleared," I mean reviewed by the Food and Drug Administration. This is a tremendous research project, for each firm.

Mr. DIXON. I think that is pretty plain. There is only one company in the United States, Upjohn, that sells this product, and it is sold here by virtue of a license from Hoechst of Germany. Upjohn buys it in bulk.

Dr. SMITH. But there are a number of firms interested in this, exploring it and making it available for clinical testing.

Mr. DIXON. Not Orinase, sir. There is an exclusive license on that.

Dr. SMITH. We are not talking about Upjohn or Orinase. This is plural. It says development of the antidiabetic sulfonamides. There is an "s" on the end of it.

Mr. DIXON. Let's go to the next classification here.

Under point No. 2 on page 4, you say "Discovery and development of the sulfa drugs."

As I understand it, sulfas are a European development and a European discovery.

In 1908, Paul Gilbo, a graduate student at the Vienna Institute of Technology, synthesized a white powder known as sulfanilamide. He described it in detail in a doctoral thesis published in that year. The fact of publication made patent monopoly impossible. The next year, I. G. Farben, in Germany, discovered it had use as a dye, and in 1932 this same German company discovered it had remarkable therapeutic use and started marketing the product under the trade name Prontosil. Subsequent to this basic breakthrough, drug companies all over the world engaged in molecular experimentation, and a number of the improved modifications are now on the market. These include, among others, Elkosin, which is Swiss Ciba; Sulamyd,

which is U.S. Schering; Sulfathalidine and Sulfasuxidine, Merck; Gantrisin, Swiss parent of Hoffmann La Roche.

Do you still stand by your statement that these were discovered by American industry?

Dr. SMITH. I certainly do, and I will explain why.

Mr. DIXON. All right.

Dr. SMITH. Sulfanilamide precursor was discovered by a German worker who, incidentally, was looking for a better dye for woolen goods, and he was the individual who first determine the antibacterial properties of this. It was not discovered in the 1930's. It was discovered back about 1908 or 1909. But it was ignored. Now, sulfanilamide, or the precursor of sulfanilamide was discovered in Germany. One other sulfanilamide was discovered abroad that was in common use. That is the one by the Yand, Baker people in England. More than 5,000 compounds have been explored in America and the ones that are in common use here for infectious diseases are an American industry contribution.

Mr. DIXON. But the major breakthrough of the discovery was German, and you would concede that?

Dr. SMITH. No, because sulfanilamide had limited usefulness, very limited usefulness. It is like opening a door so you can see beyond. You walk through the door and then you try to find out how to make use of the items that are beyond the door.

Mr. DIXON. Who opened the door originally?

Dr. SMITH. In this particular instance, one German worker looking for a better dye for woolen goods.

Mr. DIXON. All right, sir.

On page 5, the next to the last example in your list reads—

Discovery and development of the antipsychotic drugs for treating mental illness.

I understand from the hearings which have been held here that the major drugs for the treatment of patients in mental hospitals are the phenothiazine derivatives. Thorazine is the trade name of one of these drugs whose generic name is chlorpromazine, and Compazine is the trade name of prochlorperazine. Both of these drugs were developed in the laboratories of the French firm of Rhone-Poulenc, which holds, as I understand it, the U.S. patent rights. The French company has granted the exclusive right for marketing these products in the United States to Smith Kline & French, which has so testified.

The discovery of the tranquilizing properties of the phenothiazine drugs arose out of the French search for antihistamines and the potentiation for anesthetic drugs. Also, this is similar to Sparine, which is a phenothiazone derivative closely resembling Phenergan, we were given to believe. Both were developed by Rhone-Poulenc and exclusively licensed to American Home Products when only Phenergan's antihistaminic properties were known. Because the structure of Sparine had already been published and was in the public domain, American Home Products could only get a composition patent on Sparine. They could not get a product patent.

Now, another important tranquilizer——

Senator KEFAUVER. Do you want to take all the tranquilizers together? Are Miltown and Equanil included in your list?

Mr. DIXON. The next one I have is a tranquilizer known as reserpine, which in its crude form is rauwolfia. It had been used for centuries in India and in other countries for mental illness. The finishing work on the isolation of the essential alkaloids in the crude compound was accomplished in the laboratories of Ciba, Switzerland. A U.S. patent was granted this company in July of 1956.

Another tranquilizer in wide use for milder mental cases, of course, is meprobamate. It is marketed in this country under the trade names Miltown and Equanil. Meprobamate is a molecular modification of mephenesin and was discovered in England by Dr. Frank Berger who had migrated from Czechoslovakia. No patent was issued on mephenesin, but after Dr. Berger arrived in the United States, he worked for Carter Products and developed meprobamate upon which a patent was secured in 1955.

Now, do you still stand by your statement as to the discovery and development of the antipsychotic drugs for treating mental illness?

Dr. SMITH. Yes, sir. To begin with, I have before me a list of more than 20 ataractic agents, and so I think that there are many more that could be added to the list. But I think this statement is kind of clear, isn't it:

Discovery and development of the antipsychotic drugs for treating mental illness.

Mr. DIXON. As I understood from our hearings on tranquilizers, I believe over half of the total sales for the mentally ill confined to institutions is in the strong, potent type tranquilizers. It is that type of high potency tranquilizer that the institutionalized mental patient must take. The rest of us take the low potencies, the mild ones.

Now, it is that high potency type that was developed in France, was it not, sir?

Dr. SMITH. Chemically.

Mr. DIXON. Chemically?

Dr. SMITH. That is my understanding.

Mr. DIXON. The research and discovery took place there, and the patent was obtained in this country by Rhone-Poulenc.

One of our witnesses here, Dr. Hans Lehmann, of Canada, discovered the tranquilizing properties of the drug, but he was working with Rhone-Poulenc and not with any American drug firm at the time. Then Smith Kline & French ended up with the exclusive U.S. license to market that product in this country.

So do you still stand by your statement, sir, or do you want to differentiate between high potency and low potency tranquilizers in your explanation for this statement?

Dr. SMITH. No, I am talking about the role of antipsychotic drugs for treating mental illness, and one does not have to be confined to a mental institution to be in need of medication.

Mr. DIXON. All right, sir.

Senator KEFAUVER. Is it true that of these tranquilizers we are talking about, considerably over half did come from France or somewhere else, or from Ciba, Switzerland?

Dr. SMITH. That I don't know, Senator, but I do have a breakdown of the ataractic market according to broad type of products.

Phenothiazines represent roughly 45 percent, and the meprobamate type did about 38 percent, and all others about 17 percent.

These obviously are going to vary, and I am sure will vary as new substances come along, or even as the competitive advantages or therapeutic advantages of some are revealed. But I can't tell you what the percentage is that is in use in this country that have been discovered elsewhere.

Mr. DIXON. Doctor, I cite now the first example on your list on page 4, "discovery and development of vitamins B_1, B_6, and B_{12}."

According to my information, vitamin B_1, which is thiamin, was the first member of the B complex to be identified chemically. In 1926 vitamin B_1 was isolated in comparatively pure crystalline form by the Dutch scientists Jansen and Donath, but in insufficient quantities to determine its chemical structure. Ten years later, 1936, Williams discovered the structure which was verified by synthesis the same year.

Williams, as we understand it, got in touch with Merck and thiamin was then synthesized in Merck's Laboratories by Dr. Williams of Bell Laboratories in collaboration with Dr. Cline and Merck chemists.

Vitamin B_1 was first produced by Merck using a process invented by Williams. Merck was, we understand, the first commercial producer.

Using that as the example, I would say that they certainly played a vital role in its development. But would you say that they discovered it?

Dr. SMITH. In view of your statement about the Dutchmen, there might be some question. Frankly I don't know about the Dutch discovery. My knowledge only goes back to Williams.

Mr. DIXON. But, Doctor, all I am trying to do here is to get the record as nearly accurate as possible. It is not my intention to cast any reflection upon what the industry has done, but the inference I get from your statement is that they have been responsible for all of these great lifesaving discoveries that have been eventually brought to the American public and which are certainly beneficial to the American public.

I could refer to other examples on the list that you have submitted. But I think, Mr. Chairman, in order to complete the record, I would say that we should insert some tables at this point.

I believe, Mr. Chairman, that we have reached exhibit 223.

Senator KEFAUVER. We have to mark all of Dr. Smith's exhibits.

Mr. DIXON. They are all part of his statement, and they will go right with it.

Senator KEFAUVER. All right.

Senator HRUSKA. If counsel will yield at that point, I am sure counsel is entitled to his inference that there is implied in the language on pages 4 and 5 the idea that there is a claim for sole discovery and development and authorship and inventiveness, and so on.

As I say, counsel is entitled to his inference. I should like the record at this point to show that that is not the inference which the Senator from Nebraska draws from that language. I think the language is very fair.

It says, again, I read:

A few of the major breakthroughs made in medicine and other medical areas in recent years, breakthroughs that are attributable in some significant way to the laboratories of this industry.

I think that is a very modest, a very moderate statement. I should like to make this observation, that regardless of where the basic ingredient may have originated, the fact is that it is through the laboratories of this industry we find it channeled into the ultimate use to which it is put. And I believe that is the spirit in which it is set out here in this statement.

That, Mr. Chairman, is the inference and the implication which I draw from this language.

Senator KEFAUVER. We should get this point straightened out. Following the sentence you quoted, the words "discovery and development" are used.

Senator HRUSKA. I would like to submit again, it is not a discovery and development. It is something that is attributable in some significant way to the laboratories of the industry, to the discovery and development, and the original discovery of any of these basic ingredients won't mean anything unless they are adapted to therapeutic uses in proper fashion and distributed.

Senator KEFAUVER. Here is my feeling about it. I am all for research, and I am for American companies, American universities, American hospitals, American individuals, and American Government all doing what they can. They have all made significant contributions. Physicians, scientists, pharmaceutical companies, and other countries have made substantial contributions. I think we ought to try to make as clear as possible the history of these various drugs, where they came from, where they started, who made the breakthroughs, and what was done to the drugs, so that the record will be meaningful and factual. That, I understand, is what our purpose is.

We are proud of all the discoveries and all of the breakthroughs that have been made by American pharmaceutical companies. They are substantial. Nobody wants to take away any credit from them. I think that the whole story ought to be put in the record as factually as we can get it.

Mr. DIXON. Mr. Chairman, I think at this point it would be well to put into the record a number of tables which list examples of drugs that have been discovered and developed in the United States and abroad.

Senator KEFAUVER. Let them be marked.

Mr. DIXON. Let's have Dr. Blair describe them very quickly for the purpose of saving time.

The first one will be marked "223."

(Exhibit No. 223 may be found on p. 10943.)

Dr. BLAIR. The first table, Mr. Chairman, gives examples of products developed in the United States outside of universities and noncommercial laboratories. Most of these products were developed in laboratories of U.S. drug companies.

At the outset, I want to emphasize that none of these tables is meant to be exhaustive. As the headings say, they are examples of products classified according to the locus of the original development.

The next table I would like to introduce shows examples of products developed in university and other noncommercial laboratories in the United States.

Mr. DIXON. That will be "Exhibit 224."

(Exhibit No. 224 may be found on p. 10943.)

Dr. BLAIR. For example, under antibiotics, streptomycin was developed at Rutgers University, chloromycetin was originally discovered at Yale University by Dr. Paul Burkholder, and then, of course, produced commercially by Parke, Davis.

Salk vaccine, which as we know is produced by several companies, was discovered by Dr. Salk at the University of Pittsburgh.

The next table gives examples of foreign drugs in the specific product areas studied by the subcommittee. The table refers, under the heading "Antibiotics," to penicillin, which was originated in England in 1929, spiramycin in France in 1953, Griseofulvin in England in 1954, Kanamycin in Japan in 1958.

Under diabetic drugs, for example there is insulin, which was originated in Canada in 1922, and the product tolbutamide, referred to by Mr. Dixon, which bears the trade name Orinase, originated in Germany in 1954, and so on.

Mr. DIXON. That will be made "Exhibit 225."

(Exhibit 225 may be found on p. 10944.)

Dr. BLAIR. The next table gives a list of products originated in foreign countries which are not in the specific product areas studied by the subcommittee. It will be noted that one of the products under this list is aspirin, developed in Germany in the year 1898.

Mr. DIXON. That will be "226."

(Exhibit No. 226 may be found on p. 10945.)

Dr. BLAIR. If there is any one conclusion to be drawn from these various examples, it is that there are many sources of discovery of new drugs.

Dr. SMITH. Mr. Chairman, I certainly would agree with that, and that is why I feel that medical research is so big that everybody ought to have a hand in it. But I am not quite sure, and of course I wouldn't know without again referring to books and refreshing my own memory, how many of these things were suggested by industry and how many actually became possible, other than chemical curiosities, because industry was able to put them into a form that could be used by doctors for patients.

I do think that these are very interesting tables, however.

Dr. BLAIR. Mr. Chairman, the next table I have to present is based upon an annual study issued by Paul de Haen entitled, " 'New Chemical Entities,' Introduced by Seven U.S. Drug Companies, 1949–58."

Senator KEFAUVER. Dr. Smith, you are familiar with that study?

Dr. SMITH. Yes.

Dr. BLAIR. Dr. Smith has made reference on several occasions to this study by Mr. de Haen. What we have done in this table is to take the products, the new chemical entities which according to Mr. de Haen were developed during the period 1949 to 1958, and identi-

fied those introduced by the particular drug companies which have been heard thus far in our hearings.

There are seven drug companies to which our hearings on corticosteroids and on tranquilizers have thus far been extended. An example is Carter Products, Inc. It will be seen that De Haen attributes one product to Carter Products for the 10 years 1949 to 1958. That product is Miltown, or meprobamate which, as has already been noted, is a molecular modification of Mephenesin.

Under American Home Products 17 products are listed by Mr. de Haen. Three are of French origin. Six others are European in origin. Another was the result of simultaneous work in Switzerland and in a U.S. university. The remainder did not appear to be very significant products in terms of dollar value, according to our information, although they may be important for the treatment of particular illnesses.

Under Smith Kline & French, 18 products are listed. The most important, Thorazine and Compazine, as Mr. Dixon has noted, are of French origin.

In this work by De Haen, it happens that the same product is on occasion listed more than once. Compazine, for example, is listed three times in various forms, which fact of course tends to increase the number of drugs attributed to any individual company.

It will be seen that many of the drugs attributed by De Haen as having been introduced between 1949 and 1958 by one of these seven American drug companies are of European origin.

Senator KEFAUVER. That will be exhibit 227.

(Exhibit No. 227 may be found on p. 10946.)

Dr. SMITH. Mr. Chairman, perhaps Dr. Blair, since he referred to 1949 through 1958, might like to know that the latest statement by de Haen covers 1959. That embraces 63 new chemical entities.

It says that there were 36 firms with new products in 1958 that brought out none in 1959, and there were 16 firms with new products in 1959 which had none in 1958, and of these 63 new chemical entities, 20 came from Europe or were marketed by firms in the United States which are owned abroad.

Dr. BLAIR. Yes, that is correct. I was just going to ask permission, Mr. Chairman, to put in a memorandum based upon the recently issued survey by Mr. de Haen for the year 1959. But I will just read the concluding paragraph of the analysis instead.

Senator KEFAUVER. Let that be marked as an exhibit.

Dr. BLAIR. I would like to hold the memorandum, and I will just read the concluding paragraph:

> According to Mr. de Haen, of the 63 new single chemical entities introduced during 1959, 20 of them, or 31.7 percent, came from Europe or were marketed by firms in the United States which are owned abroad. Twenty-seven of the sixty-three were based on old products—either derivatives of previously known structures or new salts of old products. Adding 20 to 27, this leaves only 16 new single chemical entities which were not based on old products, left for the U.S. industry to have developed.

Dr. SMITH. This is contrary to the information that I obtained from the statement which I received from de Haen. Under new and original, there were 16 from the United States, 13 in Europe, under derivatives there were 17 from the United States, 6 from Europe, and

under new 10 from the United States and 1 from Europe. Apparently we must have different statements, Dr. Blair.

Dr. BLAIR. I believe that those are exactly the figures that I cited.

Dr. SMITH. I am sorry, I just misunderstood you.

Mr. DIXON. The exhibit should be marked "Exhibit No. 228."

(Exhibit No. 228 may be found on p. 10948.)

Senator HRUSKA. Mr. Chairman, would it be out of order to permit the witness to verify that the statement he has is identical or have counsel do it so that we can agree at least on the facts?

Senator KEFAUVER. Yes, I think that counsel should go over this with Dr. Smith and see that the statements are the same.

Senator HRUSKA. That will be fine, because we all have one object in view, and that is to get the facts straight.

Senator KEFAUVER. All right.

Mr. Dixon?

Mr. DIXON. Mr. Chairman, I think it would be of interest to put one other compilation in the record. That should be exhibit 229. I will ask Dr. Blair to describe briefly what it is.

(Exhibit No. 229 may be found on p. 10950.)

Dr. BLAIR. This is a tabulation of Nobel Prize winners in medicine and physiology for the period 1945–59.

It shows the year in which the award was granted, name of the winner, his present nationality and his nationality by birth if different, the reason for awarding the prize and the place where the research was done, where the individuals were working on the award date.

The first entry is Sir Arthur Fleming, Sir Howard Florey, and Ernst Boris Chain. The first two are British and the last German. They were given the Nobel Award for the discovery of penicillin, and they were working in London University.

Without reciting all of the other entries of the tabulation, I think a few observations are in order.

In the first place, there is only one individual in the tabulation who did his research in the laboratory of a drug company, research which earned him the Nobel Prize. The individual who received the award for the year 1948, Mr. Paul Mueller, who is of Swiss nationality, received the award for the discovery of the insect killing properties of DDT. And he was engaged in the laboratory of J. R. Geigy in Basle, Switzerland, a Swiss drug firm.

As will be seen, all of the other individuals listed in this tabulation were doing their research or were at a university when they received the award.

The second observation is that, of course, in the case of some of these individuals, it is well known that the drug companies contributed through financial assistance of one form or another to the work being carried on in the university.

It will be noted that in the year 1950 Philip Hench, Edward Kendall, and Dr. Reichstein, a Swiss, received the Nobel Prize for their work in cortisone and ACTH. The first two were associated with the Mayo Clinic, and Dr. Reichstein with Basle University.

As has already been brought out in testimony before the subcommittee, part of their work was financed by Merck. Nonetheless, the critical question on which this table sheds light is the type of atmos-

phere, the type of laboratory and the working environment in which important discoveries appear most likely to be made.

Mr. DIXON. Mr. Chairman——

Senator KEFAUVER. Let's see if Dr. Smith has any comment to make.

Dr. SMITH. Thank you, Mr. Chairman. This is rather fundamental work that these individuals were doing, and I would not be surprised if in a university atmosphere they had more time for thought to pursue some one particular avenue.

In fact, I would have been surprised frankly to learn that there were many Nobel Prize winners in industry. I think the one to be encouraged, and the Nobel Prize does this, is the individual who is working often by himself in a university.

Mr. DIXON. I would conclude that that has some connotation as to the relationship between basic research and development research that you were talking about.

Dr. SMITH. In part yes, Mr. Dixon, but there is basic research as you know going on in the drug industry, or supported by the drug industry. But unquestionably the place where most basic research goes on is in the university center.

Senator KEFAUVER. And university centers are supported by grants from the Government and from some of the pharmaceutical houses.

Dr. SMITH. And from philanthropic organizations. All three are heavy contributors.

Senator KEFAUVER. I do think, however, that the universities themselves deserve a great deal of credit.

Dr. SMITH. They do, very much.

Mr. DIXON. Then, Dr. Smith, I assume you would agree with this statement which was contained in a speech entitled, "The Washington Scene and the Drug Industry," presented at the Rutgers Pharmaceutical Conference on May 14, 1958, by Mr. Karl Bambach, executive vice president of the American Drug Manufacturers Association. I will read it to you. It is very short:

> Another policy of NIH is to favor basic research, feeling that applied research and drug development are the proper functions of private organizations. It is important that this distinction be maintained for two reasons. First, industrial research must necessarily emphasize the applied or developmental type. The drug industry carries out quite a lot of basic research, but it cannot justify undue emphasis upon search for basic facts without known commercial application. Therefore, if the Government does not provide the necessary emphasis upon basic research, this vital factor will be neglected in the Nation's total effort.
>
> Second, applied research has for its main goal the development of new products, and if the Government throws its tremendous monetary weight into applied research in a specific medical area, industry must inevitably withdraw from that field.

You would agree with that statement?

Dr. SMITH. In general principles, I think I would, Mr. Dixon. I think the Pharmaceutical Manufacturers Association is on record as supporting the Government's interest in basic research, and in the support of the training of individuals who can be of assistance in this field. And the drug industry is determined to spend some of its funds on basic research, but at the same time do what it can to make available the findings that stem from basic research and from other research for the doctors.

Senator KEFAUVER. One other question. I don't know whether we will get this completed tonight or not, but while we are on the subject of research, and I note that Senator Hruska and Mr. Chumbris want to ask some questions, in your chart, Dr. Smith, following page 18, entitled "Drug Industry's Percentage Spent on Research"—I assume that means percentage of sales?

Dr. SMITH. I am sorry, sir.

Senator KEFAUVER. 9.5 percent in 1958.

Dr. SMITH. Oh, yes, sir.

Senator KEFAUVER. You have that? The chart follows page 18.

Dr. SMITH. Yes, I have it now.

Senator KEFAUVER. You give the sources here. One is American Management Association, September 1959; the other is, American Druggist. Will you furnish the basic material upon which you base that figure?

Dr. SMITH. Yes, I can, sir.

In addition, the Pharmaceutical Manufacturers Association has undertaken its own surveys and has information to support this more than 9 percent investment in research.

Senator KEFAUVER. We have had several companies before us who gave somewhat different figures. These figures will not be exact, but Schering, Upjohn, and Merck were in a range of 7, 7½, or 8 percent. American Home was 3 percent. Carter was way down. Only one, Ciba, was listed as 13 percent, but when we asked them to take out the percentage of Ciba, Switzerland, that brought it down to a little less, about 10 percent.

From their annual statements, Dr. Brown has arrived at this figure for the 22 largest companies based on annual sales of drugs only, an average of 2.3 percent, which is almost the total. Their statements say they spent $146 million on research and development on drugs in 1958. This is 6.4 percent.

If the remainder of the industry, possibly small companies, spent another $24 million, which is unlikely, the percentage of sales would not reach above 7 percent. These are taken from the balance sheets and the reports to us of these companies, on what they spent.

Dr. SMITH. I believe, Mr. Senator, we have information that might be helpful to you because it is more complete.

The Pharmaceutical Manufacturers Association, at the request of the National Institutes of Health, made a survey of industry expenditures in medical research and carried this out in collaboration with the NIH. The figures which could be supplied to you along with an outline of how the questionnaire was conducted or carried out, came to over 9 percent, and this was done at the request of NIH and in collaboration with them.

Senator KEFAUVER. But your figures included development in addition to research, did it not?

Dr. SMITH. This was research and development, the development having to do with the development of research, not the development of a product.

Senator KEFAUVER. I wish that Dr. Browne could go over your figures with you, because he has taken what is listed as research by all of the 22 companies which account for practically all of the ethical drug business.

Dr. SMITH. Twenty-two companies? We have 140 members, almost, in PMA.

Senator KEFAUVER. I mean the 22 companies with the largest volume. We found generally that some of the small companies don't have as high a percentage of research as perhaps some of the larger ones.

But drug sales of these 22 companies amounted to $2.3 billion. This excludes other products besides drugs. They say they spent $146 million on research in 1958. This is 6.4 percent.

Senator HRUSKA. Mr. Chairman, I am wondering if it would be in order if the joint efforts of the National Institutes of Health and the PMA have produced this report, if it is in some suitable, convenient form, if it cannot be introduced into the record at this point, so that we may have the benefit of it.

Senator KEFAUVER. Yes; I would like to have it introduced so we can have a chance to examine it.

Dr. SMITH. We will introduce it. It will have to be tomorrow, sir. I don't have it with me. I have the summaries with me; would that be satisfactory, Senator?

Senator HRUSKA. I imagine, Mr. Chairman, it would be best to have the staff go over that material with the witness to reduce it to some convenient and suitable form, so that the record will not be too bulky, too awkward to handle.

Senator KEFAUVER. I think that would be well.

Dr. SMITH. If staff would care to go with me over to the office after we are through, I am sure we can provide it.

Senator KEFAUVER. I think they would be glad to go over.

By the way, Dr. Browne said I should make a correction. It wasn't all Government and pharmaceutical companies, and the universities themselves that were paying for the research; the daddys and papas were paying for a good many of them by their support to universities.

I think that would be well to get straightened out.

We sent out a questionnaire, as you probably know, and these are the reports to us from the companies themselves on the research on drugs only. This accounts for all of the sales of the total industry. Do the figures include for research some expenditures that might not be for drugs?

Dr. SMITH. No; I am sure it doesn't, sir.

Senator KEFAUVER. Are these based on consolidated or single reports?

Dr. SMITH. This is confidential information given to us to fill out a several-page questionnaire. This questionnaire, incidentally, was developed—this happened before I joined the PMA, but I understand from others on the staff it was developed—in collaboration with NIH. This was the kind of questionnaire suited to their needs.

Senator KEFAUVER. The question is whether American Cyanamid included all of its research or just the research of its Lederle division.

Dr. SMITH. I am sure I can get that information for you.

Senator KEFAUVER. I will ask Dr. Browne to go over this with you either tonight or early in the morning.

Mr. DIXON. Mr. Chairman, while you are on page 18, there is this statement there:

Last year the drug industry spent almost $200 million in research for new medicinal agents. That's an increase of more than five times what it spent for research and development 10 years ago.

I would like to read a statement by Mr. Chet Shaw that has come to my attention. It is from the Health News Institute, and it was before the ADMA in April 1957, and I will ask Dr. Smith to comment on it. On page 87 of this publication I find this statement:

Of course, they are estimates. You can take your choice among them. You can't prove you are right, but nobody can prove you are wrong. This industry abounds in drama and high achievement, and you are well aware that we reap a harvest of publicity in that respect.

But I, like all educators and writers, also like a few broad facts as flavoring material and copy. We don't have any. On that subject I will have more to say later.

On page 91, he says this:

And now this brings me back to one of my familiar themes. The greatest forces we have at our disposal are facts. In the past we have exhibited not so much a reluctance, perhaps, in revealing the facts as a failure to recognize how impressive they would be if we not only revealed them, but broadly proclaimed them.

Take as an example the perennial question as to how much the pharmaceutical industry spends annually for research. We have done a lot of talking about an estimated $100 million, but we would be hard put to document it.

What if someone questioned it, someone whose voice we couldn't afford to ignore? In this area, our truth offensive is blunted or perhaps I should say has been blunted, because I have just learned that the ADMA is going to collect accurate figures which can be widely used.

On page 92, this is said:

In general outline, we know our rebuttal is valid, but to make it convincing and at the risk of sounding like a stuck needle on a talking machine, we have to have the facts.

Of course, there is that oft-quoted study of a Philadelphia physician on the comparative cost of the case of lobar pneumonia today and before the advent of of the sulfonamides. It is a persuasive story which dramatically spells out the value of modern drugs not only in dollars-and-cents terms, but in the saving of human life which cannot be evaluated.

But we have used it and we have almost worn it out. Weapons in the war of ideas become obsolete with the terrifying speed, almost as fast as in the arms race between nations.

Our Philadelphia story about pneumonia isn't nearly as threadbare as the Kansas City memoir I mentioned a moment ago, but it is getting a little frayed around the edges. There are other weapons in our arsenal which are beginning to show their age after doing a fine job of work.

We have told and retold how the price of penicillin has declined 99 percent since a patriotic industrywide crash program solved the problem of mass production during World War II. What we need now is the same idea with a new look.

For instance, some examples of price reductions that you have made voluntarily without the goal of competition, and while you still remain the patent on the compound.

Senator KEFAUVER. Who said this?

Mr. DIXON. This is Mr. Chet Shaw.

Senator KEFAUVER. Who is he?

Mr. DIXON. As I understand it, he is with the Health News Institute; is that correct?

Dr. SMITH. No; he has been retired for some time.

Senator KEFAUVER. He was with the Health News Institute when he wrote this?

Mr. DIXON. He was the executive vice president, I understand, in April 1957, when he made this statement.

We have heard many references to the amount of money that the industry spends on research. Dr. Smith, you comment on this at page 18 and say you spent almost $200 million last year. Mr. Shaw said in 1957 that you would be hard put if somebody asked you to document the $100 million figure. Would you be hard put to document your $200 million figure?

Dr. SMITH. Not a bit. I don't know where Mr. Shaw got his information or why he put these interpretations on this. He is entitled, I am sure, to his own opinion.

I can only say that this represents information collected by the PMA office in a way that couldn't possibly produce weighted results, because the firms are not identified, and this we honestly believe to be truthful information shared by the firms. They had nothing to lose by revealing the information, since it was coded and therefore no one could find out the figure.

Mr. DIXON. Of course we have not probed deeply to find out what is included in research. What is the definition of research, as you understand it, when you use the figure of $200 million? Would you give us a complete breakdown of what that is?

Dr. SMITH. I think the questionnaire would be helpful, Mr. Dixon. Are you asking me about the questionnaire or my opinion of research?

Mr. DIXON. I am asking you for what that figure includes.

Senator KEFAUVER. I think the questionnaire would be the answer. If you can read that to us, that would be best.

Mr. DIXON. Does the questionnaire that was sent out include the definition of research so that the companies would be bound by that definition, or were they left to their own imagination to decide just what was research?

Dr. SMITH. We feel that it was sufficiently informative and limiting to provide the kind of information that would satisfy the NIH, and apparently it did, and us.

Senator KEFAUVER. All right, Senator Hruska, do you have any questions?

Senator HRUSKA. Not at this time.

Senator KEFAUVER. Mr. Chumbris?

Mr. CHUMBRIS. I have just a brief reference here, Mr. Chairman, on the question of research.

This is from "The Advancement of Medical Research and Education Through the Department of Health, Education, and Welfare, Office of the Secretary, June 27, 1958." I am reading from page 9:

> Before the extension of such a program above the level in the current fiscal year, thorough consideration be given to basic policy questions, to care and planning, to realistic assessment of the present state of studies of this kind, and to the effects on all medical research of absorption of resources, particularly manpower, by such programs.
>
> As a principle, the primary resource in the development and production of new drugs be the investment of the private industry, and such drugs as may result from intramural research and NIH be a byproduct of other studies and not the outcome of an NIH intermural drug development program.

Senator KEFAUVER. I am glad you read it but I don't know exactly what it means.

Mr. CHUMBRIS. The main point is the primary resource in the development and production of new drugs be the investment of private industry rather than be undertaken by the NIH or the Department of Health, Education, and Welfare.

Senator KEFAUVER. Mr. Kittrie.

Mr. KITTRIE. Yes, Mr. Chairman. I would like to ask a few questions. I will make them very short.

Senator KEFAUVER. Very well.

Mr. KITTRIE. I would like to start out by calling further attention to a very appropriate and important statement made by Senator Hruska a little while ago, when he said that quite often what counts most is not who made the actual discovery of a new drug, but who is responsible for bringing it into the market and to the eventual consumer. Developing a drug is as important as inventing it.

We had Dr. Berger here, who testified that he did research in England. He discovered some of the drugs that are now used for the treatment of mental illness, yet he testified here that it was only after he came to the United States, and after he came in contact with the American drug companies that his drug was finally manufactured and finally reached the consumer. The competitive and profit motive of the American companies played an important role in this.

I think Dr. Berger's case gave a very interesting illustration of the fact that discovery is not all. Due to the fact that there was no strong competitive element in the British drug industry, and due to the fact that the profit motive was not strong there—nothing was done about his discovery.

In evaluating what the American drug industry has accomplished, I think it would also be interesting to look at some figures that I obtained, at Senator Wiley's request, from the Library of Congress concerning exports and imports of drugs.

For example, just before the Second World War, we had many more drugs imported to the United States than exported. This picture has changed dramatically since the end of the war. In 1939 exports of drugs totaled only $20 million. In 1958 exports totaled $278 million. This is an increase of almost 1,400 percent increase in drug exports. This indicates to me that the drug industry has been doing some tremendous work. For this the drug industry should receive credit. Especially these days, when we are concerned about the ability of our products to compete in foreign markets—the record of the drug industry is most impressive. This growth, furthermore, would possibly not have been accomplished if the industry had not had enough profits to pay for research and development.

I would like to make one additional comment, and this on the question of who invented what drugs. I was impressed with the listing of all the foreign scientists who received Nobel prizes. I was very impressed to see how many of these drugs were discovered in other countries. Yet nobody would seriously claim that this is due to the inferiority of the American creative genius. This evidence apparently seems to indicate we need more money for research in this country, more research facilities, and more scientists.

I think we also have to remember that the pharmaceutical industry in other countries has a much longer tradition than our own pharmaceutical industry. Germany and England are countries with long traditions in this field.

I meant to ask a question, instead—I made a statement. But I would like to have Dr. Smith's comments to any part of the statement I made here.

Dr. SMITH. Thank you, sir.

You reminded me of something that I meant to comment on when Dr. Blair offered information on the discoveries abroad.

In 1950 I attempted to learn if it was possible to publish several foreign editions of the Journal of the American Medical Association, because we had been requested by several people from Washington to look into this possibility, it being felt that American medicine, portrayed abroad so to speak, would be helpful to the individuals abroad, and also would be helpful to Americans.

I looked very carefully into this and consulted many, many times and spent many hours with individuals in Washington and elsewhere. I made a number of what I would call studies, because they were based on personal interviews with individuals abroad, since I was traveling quite a bit for the World Medical Association, and a very significant observation came to my attention.

We considered the various ways in which a foreign edition of the Journal might be made available, whether it be in capsule form whether we could send plates abroad, or whether we could airmail copy and have it printed abroad. There were several possibilities.

The best way, I thought, would be an abbreviated form of the Journal in which we removed American advertising and, certain other sections that I thought would have limited appeal to the doctors abroad.

But the thing that they asked most of me in Switzerland and Germany and Italy and France and various places was this:

"Will you please not remove the advertisements from the Journal of the American Medical Association?"

I asked them why, and they said, "In most instances, we don't have the drugs, but someday we hope to."

And I thought that that was a most significant comment on how America was leading the world.

Mr. KITTRIE. Thank you very much.

Senator KEFAUVER. All right.

Is there anything else before we recess?

Senator HRUSKA. May I inquire what the program is for the rest of the week?

Senator KEFAUVER. As I stated earlier, we had some witnesses from Consumers Union who were to be here tomorrow. They have agreed to come later on. We have two witnesses scheduled to come on Thursday. We have advised Pfizer to be here if they have something to say about them, but they have indicated they just want to file a statement in response.

We have set aside our witnesses in the morning so as to finish with Dr. Smith in the time that we will have available. The Senate meets, I believe, at 10:30 tomorrow. I think that we will recess now until 9:30.

Mr. CHUMBRIS. I was afraid you were going to say 5:30.

Senator KEFAUVER. That is the program.

Senator HRUSKA. That is fine. I assume that the rule is that copies of statements are filed 24 hours before they are given? Is that one of your rules?

Senator KEFAUVER. We ask for statements and we try to get witnesses to file them 24 hours in advance.

Senator HRUSKA. I assume that the witnesses who are to appear tomorrow but who will not appear until Friday, that their statements are prepared by now. May we have them in the morning?

Senator KEFAUVER. Sometimes they don't have facilities to make copies and then we have to get them mimeographed here.

We don't hold strictly to that rule. We try to do the best we can. We will get them to you as quickly as possible.

Senator HRUSKA. Thank you.

Senator KEFAUVER. All right.

By the way, before we recess, Dr. Smith, you will be back and you will have these distinguished doctors here. We haven't asked them any questions, but we don't want to hold them up. I don't think there will be much time to ask them any questions.

Dr. SMITH. They have expressed a willingness to try to be helpful to the committee, sir; and will be here tomorrow, if you need them.

Senator KEFAUVER. Very well.

We will stand in recess until 9:30.

(The prepared statements filed by Dr. Smith follow:)

PART I

Mr. Chairman, members of the subcommittee, my name is Austin Smith. I am president of the Pharmaceutical Manufacturers Association and am also president of the Health News Institute. For some years I was editor and managing publisher of the Journal of the American Medical Association and of other scientific publications sponsored by that association. I am chairman of the board of directors of the U.S. committee and council emissary of the World Medical Association, and have served as executive editor of the World Medical Journal.

I also have served in various official capacities for bodies such as the U.S. Pharmacopoeia, medical and other organizations, universities, and scientific societies. I also am a member of a number of professional and scientific associations.

I received my degree, M.D., C.M., in 1938 from Queen's University, Ontario, and a master's degree in medical science from the same institution in 1940.

The Pharmaceutical Manufacturers Association, which I represent, is composed of 138 firms engaged in the manufacture of ethical, or prescription, drugs. As an addenda to this statement, I am submitting a detailed description of the functions and organization of this association.

In preface to my testimony, may I point out that my purpose is to give a complete picture of the operations of this industry—one of the finest examples of how the American free enterprise system functions in the public interest and for the public welfare.

There is, as you know, grave danger of misinforming the public when attention is directed toward the single product of a single company—toward the isolated price charged by another company—without relating these to the many thousands of products produced by the entire industry. As a matter of fact, the industry has an outstanding record of low prices maintained in an inflationary period when prices of other commodities have climbed at far faster rates.

In my testimony today, I will demonstrate that the competitive pharmaceutical industry in America has played a role unparalleled elsewhere in the world in reducing human suffering, in helping to eradicate diseases which have crippled mankind for centuries.

More than that, I will show that the revolutionary advances of recent years in the drug field have been the direct result of the competitive forces at work within this industry—which is, by many of the measures used by economists, one of the most competitive in the Nation.

Further, I will illustrate the fact that the profit incentive in the drug industry has served the public interest by driving prices down to the lowest levels that can be maintained while still supporting the future growth and discovery.

In fact, Americans today would be paying a billion dollars a year more for drugs if the price of medicine in the past few years had gone up only as much as the total cost of living.[1]

On the basis of the record I shall explore, I know of no other American industry that has contributed more from its resources to the public welfare—

Through research on problems that affect the lives and health of every individual;

Through effective and constructive use of profits for discovery and growth;

Through mammoth tax savings to the public by reducing the cost of public health services;

Through maintenance of a reasonable price level in an inflationary period;

Through cooperation with Government in working toward the highest standards of quality, purity, and control of its products;

Through creation of a distribution and information network unrivaled anywhere else in the world to make available the newest and the best life-giving and pain-relieving medicines whenever and wherever they may be needed; and

Through efforts to solve the challenging health and welfare problems still confronting us.

The record will show, Mr. Chairman and Senators, that no other American industry has devoted a greater proportion of its resources to provide such great social benefits for the vast majority of our citizens.

Let me cite, for instance, a few of the major breakthroughs made in medicine and other medical areas in recent years, breakthroughs that are attributable in some significant way to the laboratories of this industry:

Discovery and development of vitamins B_1, B_6, and B_{12}.

Discovery and development of the sulfa drugs.

Synthesis and discovery and development of high potency corticosteroids.

Mass production of penicillin.

Discovery and development of the other broad-spectrum antibiotics.

Development of more effective diuretics.

Antineoplastic research resulting in valuable palliative treatments for cancer.

Establishment of the role of folic acid in human nutrition.

Application of tissue culture research which aided in the development of antiviral vaccines.

Development of the antidiabetic sulfonamides.

Discovery and development of the antipsychotic drugs for treating mental illness.

Discovery and development of the hydrazide derivatives for treatment of tuberculosis.

Many others.

Lest the inference be drawn that I am overstating the industry's contributions to good health through an excess of zeal, I want to cite a few statements coming from authorities outside the pharmaceutical industry. In any profession as technical and wide ranging as medicine there can be disagreement among individuals about the significance of the contributions of any segment of the broad field. Some such disagreements have come to public attention during earlier sessions of this subcommittee. The quotations that follow, on the contrary, represent the responsible opinion of officials of unquestioned authority.

Dr. James Watt, Director of the National Heart Institute: "The major strides in drug discoveries of the past few years * * * have been made within commercial pharmaceutical houses."[2]

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[1] Backman, Jules: "What Does Medical Care Cost?" Journal of the American Pharmaceutical Association, October 1959.

[2] Special report on "Development of New Cardiovascular Drugs," submitted by Dr. James Watt in hearings of subcommittee of Committee on Appropriations, U.S. Senate, 86th Cong., May 6, 1959, p. 614.

Dr. Robert H. Felix, Director of the National Institute of Mental Health: "I believe that these (psychotropic) drugs have created more collective enthusiasm and more cooperative endeavor throughout psychiatry and allied sciences than any other single development over the past three or four decades. With the advent of ataractics, the stereotyped picture of the mental hospital—the locked and barred institution—is rapidly disappearing." [3]

Dr. Henry Brill, deputy commissioner of mental hygiene, and Robert E. Patton, of the department of mental hygiene, State of New York, in a paper on an "Analysis of Population Reduction in New York State Mental Hospitals During the First 4 Years of Large-Scale Therapy with Psychotropic Drugs." "* * * The authors came to the conclusion that the abrupt population fall (1955 to 1956) was in material degree due to the introduction of the new drugs * * *.

The official Hinchliffe report to the British Ministry of Health: "* * * all subsequent antibiotics (after Waksman's discovery of streptomycin on a grant from a drug company) have been discovered by scientists working in the laboratories of pharmaceutical firms, almost all in the United States of America." [4]

The evidences of substantial contributions to the national welfare transcend by far the individual dissents coming from physicians who cannot speak for organizations representing mass medical experience, and the examples cited above are only a few of them. In addition, spokesmen for the Veteran's Administration have reported dollar savings to the Government by reason of the increased effectiveness of drugs, specifically in the treatment of victims of tuberculosis and mental disease.

Furthermore, there has been no missile gap in pharmaceutical research. While the U.S. pharmaceutical industry has been leading the world in the development of new medicaments, spurred by the incentives of the free enterprise system, the Soviet Union has all but dropped from the race. No single new drug is attributable to Russia in the 42 years that have passed since the October revolution. On the other hand, the U.S.S.R. has freely pirated American developments and is selling identical drugs in world markets at a price advantage, presumably as part of its effort to buy the friendship of uncommitted nations.

Nevertheless, the pharmaceutical industry in this country shows no signs of diminishing vigor. On the contrary, it has constantly stepped up its investment in new plant and equipment and in research. Since 1947 this industry has spent about $1 billion in research alone. (See chart.)

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[3] Felix, Robert H.: Speech "Psychotropic Drugs—Pacemakers in Research and Treatment," Philadelphia, Jan. 27, 1960.

[4] Hinchliffe committee: "Final Report of the Committee on Cost of Prescribing," London, 1959.

MAJOR RISKS must be met out of PROFITS

1 Many costly research projects fail completely

-In 1958 out of 114,600 substances tested about 40 became marketable drugs.

the failure ratio is 2,865 to ONE!

2 Some drugs successful in clinical tests, disappoint in actual practice

-Undesirable side effects OCCUR — doctors' and patients' preferences change.

3 Competition rapidly obsoletes a successful drug.

Source: (Item #1) PMA Staff Computation

You can understand the significance of this staggering investment better when you realize that research represents perhaps the major risk in the drug industry. The chance that any given research involving a new potential medicine will be successful stands at 2,865 to 1 against the manufacturer.

And once a drug proves successful through a development and testing process that may take years, the manufacturer knows from experience that his new product may have only a brief marketable existence because of the customary high rate of obsolescence in this highly competitive industry.

CONTRIBUTIONS OF DRUG INDUSTRY TO PUBLIC HEALTH

Most of us in this hearing room were alive 25 years ago, and have lived through an era in which chemotherapy virtually has revolutionized medical science.

Twenty-five years ago, you will recall, the medical profession had only a few drugs capable of striking at the causes of infectious diseases. The list of killing and crippling diseases was long. In case after case, doctors were forced to prescribe medicines that they knew could, at best, provide only supportive therapy.

Many of us recall from agonizing personal experience, dark hours when prayer seemed to offer the sole avenue of hope toward recovery of a beloved family member or friend.

In the short period of a quarter of a century, disease after disease has been erased from the dread list of cripplers and killers.

This has been made possible in large part by discoveries and development activities of the drug industry, by chemotherapy that today permits a physician to treat many specific organs, and to conquer many specific diseases, with the precision of a surgeon using a scalpel.

The American lifespan lengthens

What have these plummeting death rates meant to you and to me, and our families?

More than 3 million Americans, living today, would be dead if the Nation's death rate had remained constant at its 1937 level.[5] Statistically, this would involve about 12 of those present in this hearing room. (See chart.)

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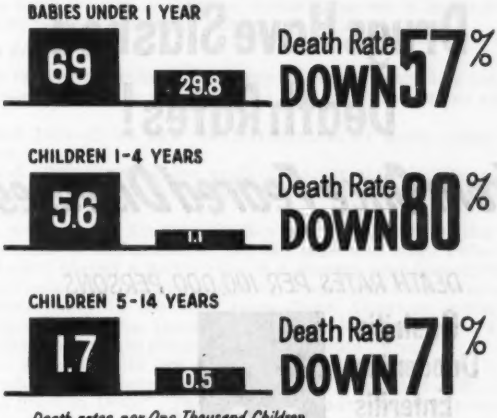
[5] PMA calculation based on mortality statistics compiled by U.S. National Office of Vital Statistics.

Your Babies and Children Live Longer

NEW DRUGS have played A KEY ROLE

Death Rates Plummet!



Death rates per One Thousand Children by age group – 1930 and 1958

Source: "Statistical Abstract of the United States 1959," p. 63 p. 66

Between 1930 and 1950, the death rate for babies under 1 year was cut 57 percent; for children 1 to 4 years was reduced 80 percent; for children 5 to 14 years was reduced 71 percent.[6]

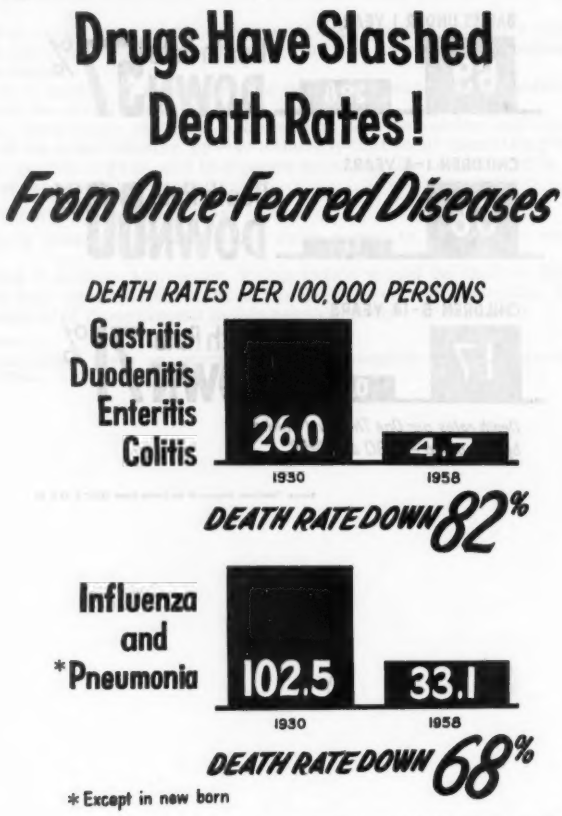
Only as recently as the years 1930 to 1934, 1 of every 157 mothers died at childbirth. From 1 out of 157, this number was slashed to 1 out of 2,222 in the 4 years ending in 1958.[7]

In the past 30 years alone, modern drugs have helped add nearly 10 extra years to the U.S. lifespan.[8]

The conquest of disease

Let us examine for a moment a partial list of diseases that have fallen before the combined attack of modern drugs and advanced medical techniques:

At the turn of the century, pneumonia and influenza, tuberculosis and gastritis accounted for 1 of every 3 deaths in the Nation.[9] Recoveries from pneumonia, you may remember, began to rise sharply simultaneously with development of sulfa drugs, continuing with the introduction of penicillin and other antibiotics. (See chart.)



[6] Statistical Abstract of the United States: 1959, p. 63.

[7] Report by U.S. National Office of Vital Statistics.

[8] Report of the PMA to the Committee of Consultants on Federal Medical Research of the Senate Appropriations Committee, Dec. 4, 1959.

[9] Health Information Foundation, "Control of the Communicable Diseases," Progress in Health Services, vol. VI, No. 4, April 1957, and "Changes in Leading Causes of Death," Progress in Health Services, vol. V, No. 3, March 1956.

Since 1930, pneumonia and influenza death rates have dropped 68 percent. The death rate from such killers as gastritis, duodenitis, enteritis and colitis has fallen 82 percent.[10]

In the 13 years from 1944 through 1957, the death rate from tuberculosis fell 80 percent. The list is long. To cite only a few more examples, the death rate in that same 13-year period dropped 76 percent for meningococcal infection, dropped 78 percent for mastoiditis and ear disease, dropped 74 percent for syphilis, dropped 93 percent for whooping cough, dropped 90 percent for scarlet fever, dropped 96 percent for diphtheria.[11]

In short, the availability of new and improved drugs has meant life itself to many of us in this room, to our families—to millions of Americans who, without proper medication and treatment, would have died from these once-feared diseases.

I might add that the most spectacular results are those which are translatable into terms of life and death. There are other benefits. Modern drugs have cut the incidence of complications for sufferers from infection, have made possible surgery that could not be undertaken in earlier years, have made people socially more effective, have brought unique and special progress in fields such as mental health, and have helped to alleviate pain.

The parade of discovery

The parade of pharmaceutical discovery in recent years has transformed the field of medicine. Each new discovery has toughened the armor against disease and illness.

In the period 1931–40 we saw the introduction of sulfa drugs and the synthetic vitamins.

In the period 1940–53 came the synthetic antimalarials, the antibiotics, the antihistamines, the synthetic hormones, the amino acids, and anti-tuberculars, and the radioisotopes.

Since 1953, we have had the introduction and availability of the tranquilizers, the psychic energizers, the diuretics, and the polio and other anti-viral vaccines.

Private industry played a major role in discovery and development of almost all these medicinals. All but one antibiotic discovered since World War II and produced commercially in the U.S. came from American research. And of these antibiotics, every one, including the four broadspectrum antibiotics, resulted from efforts of private pharmaceutical manufacturers.[12]

These great developments are continually being superseded by even better and newer medications. Seven out of every ten prescriptions filled today could not have been filled in 1935.[13] The spectacular advance in pharmaceuticals was brought out in earlier testimony by one witness who pointed out that most of the hundreds of different products created or marketed by his firm are no longer being made. They have been replaced by better, more effective products. More than 65 percent of this company's business is in products that did not even exist 5 years ago.[14]

How new drugs have cut health bills, saved tax dollars

As I have stated, the most important contribution of the ethical drug manufacturing industry to our society has, of course, been in the field of saving human lives.

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[10] Statistical Abstract, op. cit., p. 66.
[11] PMA, op. cit.
[12] McKeen, John E.: "The Pharmaceutical Industry," a speech, March 5, 1959.
[13] PMA, op. cit.
[14] Brush, Alvin G.: Statement before Senate Subcommittee on Monopoly and Antitrust, Jan. 27, 1960.

But, in addition, every major advance of the U.S. drug industry has also been accompanied by astronomical dollars-and-cents savings to the American people. I refer specifically to the vast reduction in medical expenses made possible by rapid cures for illnesses, to the shorter length of hospitalization which results, to the increased productivity of those to whom new drugs have made cure possible.

The dimensions of these savings are so great that only an indication of their scope is possible.

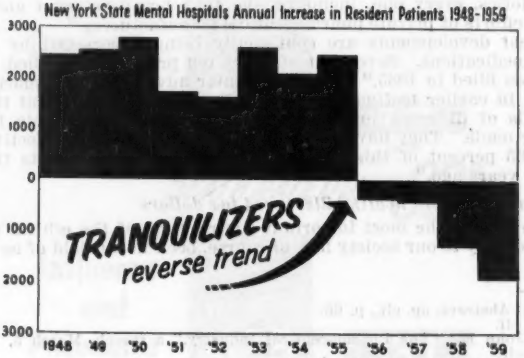
The National Health Eduction Committee has reported, however, that in just one year the U.S. Treasury gained more than a billion dollars—and almost $6 billion was added to national income—as a result of the decline in mortality rates since 1937.[15] (See chart.)

TRANQUILIZING DRUGS
are cutting
mental hospital population

Returning thousands of patients to useful lives

Saving millions of taxpayer dollars

New York State Mental Hospitals Annual Increase in Resident Patients 1948-1959



Source of chart: "Analysis of Population Reduction in New York State Mental Hospitals During the First Four Years of Large-Scale Therapy with Psychotropic Drugs"; Department of Mental Hygiene, State of New York

[15] McKeen, John E., op. cit.

In the field of mental health, the use of psychotropic drugs made possible savings of an estimated $860-million in State mental hospital construction in a single three-year period by reducing the length of hospitalization for thousands of patients.[16]

This subcommittee has in earlier testimony received authoritative estimates that steroids are capable of restoring 1,020,000 Americans (34 percent of those now suffering from rheumatoid arthritis) to a more productive life. A conservative estimate of savings through increased productivity and lowered cost of care for these million people has been placed at over a billion dollars a year.[17]

We cannot close our eyes to the fact that the priceless therapeutic dividends resulting from new drugs and other achievements of the health team are also accompanied by very substantial dollars-and-cents dividends to all Americans and to the Government.

I am confident that this subcommittee shares the concern of all our people that the great advances of the past—with their contributions to human health and their contributions to the American economy—continue at the same rapid pace.

These accomplishments, I submit, are the direct result of the operations of this industry under the enterprise system. Any tampering, any governmental restraints upon the healthy incentives which this system provides for new discovery and product development will inevitably slow the flow of life-giving drugs which has benefited every American and people all over the world.

COMPETITION RESPONSIBLE FOR RAPID PACE OF DISCOVERY

Any examination of the record of the drug industry must be undertaken, if it is to serve the public interest, in the light of the need for preserving the many-faceted, never-ceasing and highly costly explorations which have brought past gains, and which hold so much promise for the future

These discoveries, the progress of recent years, can be attributed—more than to any other factor—to the intense competition which exists within the drug industry. This is a matter of primary interest to this subcommittee, vested with responsibility for investigations in this field. On the basis of the record, this subcommittee will have to conclude that the ethical drug manufacturing industry is one of the most competitive it has ever examined.

More than 1,300 companies manufacture prescription drugs in this country, with no one company accounting for as much as 10 percent of total sales. This degree of competitiveness is approached by few other industries. Compare it with the big five companies that dominate cigarette manufacturing, with the big three in the automobile field, the big three in business machines, the big four in aluminum, the big four in meat packing. Or contrast it with the fact that one company accounts for half of all automobile sales. One steel company accounts for about 28 percent of all American steel production.

In drug manufacturing, the record of individual companies has been characterized by fluctuation both in volume of sales and in rank in the industry's total sales picture. This is highlighted by a recent study af the 10 leading companies for the years 1957 and 1958. In this 1-year period, half of these companies changed their relative rank in the industry. Three moved up one position. One moved down two positions. One moved down one rung.[18]

In the steroid field alone, at least 12 of the companies offering prescription products were not selling this type of drug 2 years ago. One company, not even in the field in 1957, took over fourth place in sales in 1958 by developing one new drug.[19]

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[16] National Committee Against Mental Illness, Inc., What Are the Facts About Mental Illnesses? 1959.

[17] Gibson, Augustus, statement before Senate Subcommittee on Monopoly and Antitrust, Dec. 9, 1959.

[18] McKeen, John E., op. cit.

[19] Connor, John T., statement before Senate Subcommittee on Monopoly and Antitrust, Dec. 9, 1959.

This illustrates one other aspect of competition in ethical drugs: the relative ease of entry into the industry, and into its component fields. Even though it is by no means easy to perform a top quality job and emerge an industry leader, the history of the drug industry is marked with the founding of new companies. There are many examples of sheer competitive vigor enabling such companies to make outstanding discoveries and to assume positions of stature in the field.

While we are talking about competition—I feel I should refer to the fact that in a very recent instance the Justice Department unsuccessfully brought suit against certain companies in this industry, alleging improprieties in the marketing of Salk antipolio vaccine. Charges that the companies were guilty of a conspiracy to fix prices and terms of sale for the vaccine were widely circulated as the Government sought to prove its case. Many Americans were exposed to the charges against the companies. Far fewer, even today, I am confident, are aware that Judge Phillip Forman threw the case out of court for lack of evidence.

One of the unfortunate aspects of over-zealous activity in this field is the fact that ultimate vindication in the courts is not always enough to compensate fully for the damage done by unjustified and highly publicized attacks.

Any analysis of this industry in the context of antitrust or monopoly factors should take into full consideration a basic characteristic which is the antithesis of that existing under monopoly conditions: the high rate of obsolescence of prescription drugs. It is axiomatic that monopolies are resistant to product change—that the tendency, under monopoly conditions, is to prolong the life of a product.

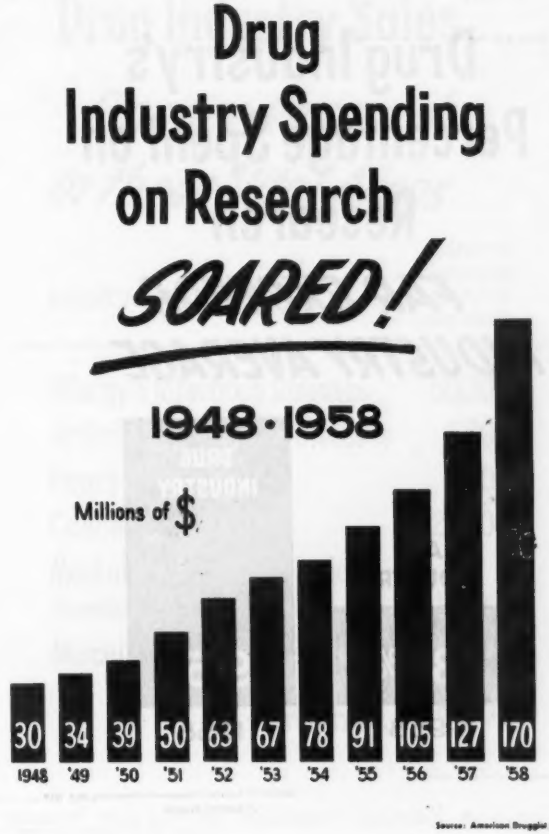
In the drug industry, competition forces each company as a matter of economic survival to dedicate itself to obsoleting its own products. Any slackening of competitive research carries with it the prospect of grave decline in future business. This is, of course, as it should be. The public interest in this area certainly lies in assuring that American business receives maximum incentive to direct its energies toward bettering the common welfare.

COMPETITION RESULTS IN RESEARCH LEADERSHIP

This Nation's leadership in research is admitted and recognized throughout the world. The results of this research are likewise admitted and recognized. These accomplishments must in large measure be attributed to two factors—the profit incentive and competition.

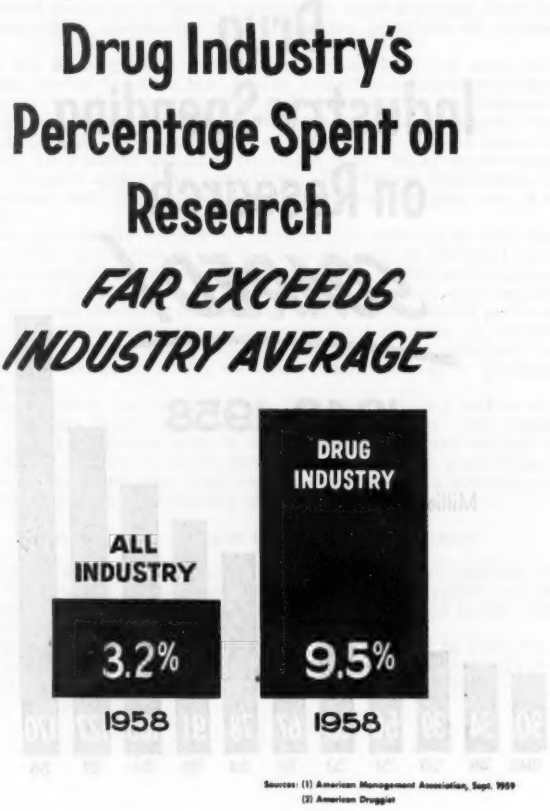
Competition in research has enabled the United States to lead the world in the output and effectiveness of ethical drubs, revolutionizing not only drug manufacturing but—as we have seen—the practice of medicine itself.

Last year the drug industry spent almost $200 million in the search for new medicinal agents. That's an increase of more than five times what it spent for research and development 10 years ago.[20] (See chart).



[20] PMA, op. cit.

While one might expect research expenditures to increase commensurately with the industry's sales volume, the rise has been far more rapid—in fact, rising from $30 million in 1948 to $170 million in 1958, an increase of nearly 600 percent.[21] (See chart.)



[21] American Druggist magazine.

It should be noted that this is three times the average for all U.S. industry expenditures for research.[23] (See chart.)

Drug Industry Sales

Finance Research in these Vital Areas

MEDICAL CATEGORIES	Number of Substances Tested in Laboratories
Allergy & Infectious Diseases	50,300
Arthritis & Metabolic Diseases	6,300
Heart	8,200
Cancer	28,000
Mental Health, Neurological Diseases & Blindness	12,100
Miscellaneous	9,700
TOTAL	114,600

Source: PMA Staff Computations

[23] "All Industry" from American Management Association, September 1959. "Drug Industry," from private PMA study.

In 1958, this tremendous concentration on research enabled the industry's scientists to test a total of 114,600 substances in laboratories, searching out new answers to the problems of allergy and infectious diseases, for which 50,300 substances were tested; arthritis and metabolic diseases, testing 6,300 substances; heart disease, testing 8,200 substances; cancer, testing 28,000 substances; mental health, neurological diseases, and blindness, testing 12,100 substances.[23]

A large part of this research activity, incidentally, was in fundamental investigation—basic research, which the National Science Foundation has defined as research on "projects which are not identified with specific product or process applications, but rather have the primary objective of adding to overall scientific knowledge."

In the last year for which figures are available, the drug industry spent between 20 percent and 25 percent of its total research budget on fundamental research, in contrast with an all-industry expenditure of only about 4 percent of total research budget for this purpose.[24]

This essential research has imposed a demand for highly specialized and talented teams of scientists, men who—when available at all—are extremely expensive elements of the cost of operation. It has been estimated, for example, that maintenance costs for just one Ph.D. scientist (salary, costly equipment and other facilities) run in the vicinity of $50,000 to $75,000 per year.

The total figure becomes formidable when you recognize that the drug industry today employs more scientists per 1,000 employees than any other industry. A recent study by General Electric Laboratories, in fact, revealed that the ratio of scientists to general employees in the drug industry is three and a half times higher than in such major research fields as the chemical, petroleum or electrical industries.[25]

An economist with the Public Health Service pointed out in Public Health Reports of October 1958, the extent to which the drug industry has found it imperative to increase its scientific manpower: "In addition to skilled operatives, clerical and other employees, drug firms reported 380 physicians in their employ as of January 1957 as compared with 155 10 years before and 65 20 years earlier. The total number of employees with graduate degrees in the medical and allied sciences was 3,000 as of January 1957 compared with 990 10 years before and 300 20 years earlier." [26]

This sharp upswing has continued, with ever-mounting demand for chemists, physicists, bacteriologists, pharmacologists, clinicians, pathologists, cytologists, microbiologists and others.

Competition, in sum, is harnessing the best minds obtainable today and putting them at work at tasks which have as their end purpose the alleviation of human ills and the broadening of medical knowledge.

DRUGS—THE REAL BARGAIN

Dr. Jules Backman, a nationally known economist and professor of economics at New York University School of Commerce, Accounts and Finance, has made a pointed observation about the price of drugs:

"If drug prices had risen as much as other prices since 1939," he said in October 1959, "it would cost the consumer at least another billion dollars to buy the drug preparations now consumed." [27]

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[23] PMA staff computations.
[24] Health News Institute, October 1959; Science Magazine, June 19, 1959.
[25] Fisher, J. C., "Basic Research in Industry," Science magazine, vol. 129, June 19, 1959.
[26] Kramer, Lucy M., "Drugs and Medicines," Public Health Reports, vol. 73, No. 10, October 1958.
[27] Backman, Jules, op. cit.

Dr. Backman's statement emphasizes a key fact about the prices of the products of this Nation's competitive drug industry in recent years. (See chart.)

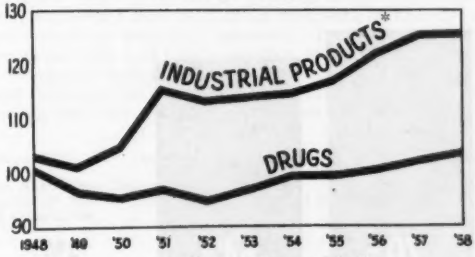
In ten years of INFLATION

Wholesale prices of Industrial Products rose 22%

BUT...

Wholesale drug prices rose only 3%

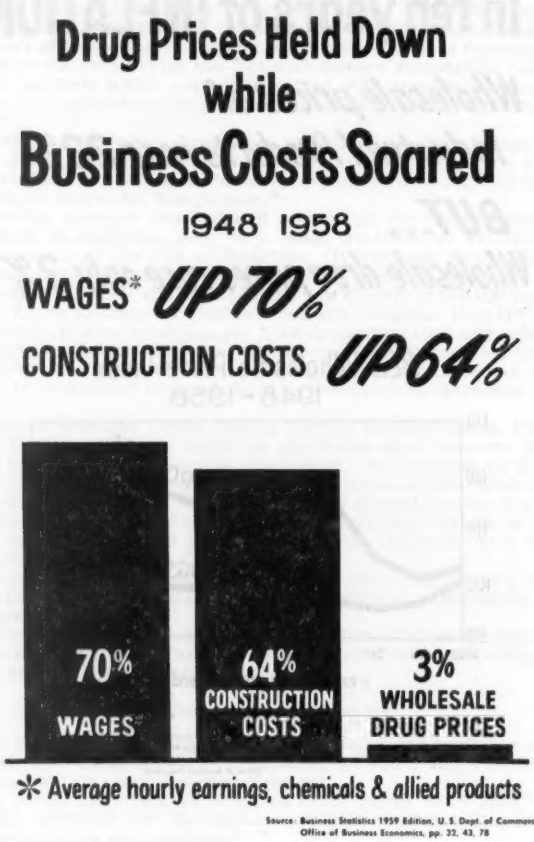
BLS Wholesale Price Index
1948 - 1958



* except farm products and foods

Source: Bureau of Labor Statistics, Wholesale Price Index for Pharmaceutical Preparations
Business Statistics 1959 Edition, U. S. Department of Commerce, Office of Business Economics

In a period of continuing inflation, the wholesale price of drugs consistently since 1948 has resisted upward pressures—rising only 3 percent in the past 10 years. This has occurred, mind you, at a time when wholesale prices of all industrial products were soaring 22 percent.[35] (See chart.)



[35] Bureau of Labor Statistics, Wholesale Price Index, 1948–58.

And it has occurred in a period when drug industry costs, far from remaining stable, were spiraling. Drug industry wages went up 70 percent, for example. In the face of great demands for expansion, construction costs shot up 64 percent.[29]

I think I should add, at this point, that several classes of the most effective new drugs produced by the industry were not on the market 10 years ago. They consequently are not included in the BLS figures. But if it were somehow possible to include them, the available evidence on the trends indicates that their inclusion would result in no substantive change in the commendable price performance record of this industry.

This subcommittee is, however, understandably interested—as is the drug industry—in the price the consumer ultimately pays for the product.

Aside from humanitarian reasons, the drug industry has a solid and logical economic purpose behind its interest in reasonable prices for consumers. Successful and profitable business operations, in this industry, are possible only if there is a high volume of sales in drugs. These sales, obviously, will diminish if retail prices are too high—if they prevent the widest possible use of the product by the consumer.

Additionally, of course, each company is confronted with constant competition from other companies within the industry—each attempting to gain a larger part of the market, each attempting to build sales by a combination of creating better medicinals and broadening their usage through prices that are lower than those other companies charge for similar products.

How do retail drug prices compare with those of other commodities essential to the U.S. citizen for well-being and security?

The fact is that since 1947–49 the retail price of drugs and prescriptions has risen, not more, but somewhat less than other elements of the cost of living (a rise of 21.4 percent compared with 23.7 percent). Rents have gone up 38.7 percent, personal care 29 percent, and transportation 44.3 percent.[30]

The American consumer today, despite all that has been said about drug prices, actually is spending about the same part of his income on drugs as in 1939, before most of our specific high potency drugs were available.[31]

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[29] Business Statistics 1959, U.S. Department of Commerce, Office of Business Economics, pp. 32, 43, 78.

[30] Bureau of Labor Statistics, Consumer Price Indexes.

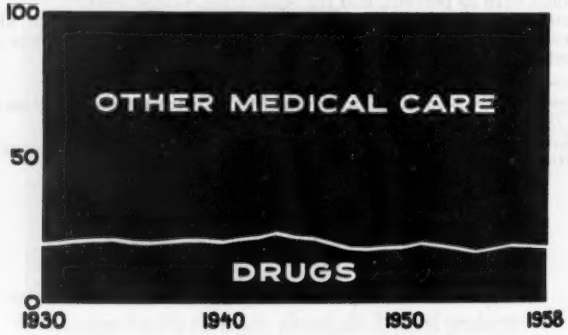
[31] Calculations based on figures published by National Industrial Conference Board and U.S. Department of Commerce.

Drug prices, in fact, have increased only about half the extent of fees for doctors and dentists—and only one-fourth as much as the rise in hospital rates.[32] (See chart.)

Today's advanced drugs take
no more of your Health Dollar
than the less effective
Drugs of 1930

TODAY 19.9 cents
1930 20 cents

Per Capita Expenditures on Drugs and Sundries as Percent Total Medical Care Expenditures 1930-1958



Source: Various issues of the Survey of Current Business, U. S. Department of Commerce

[32] Bureau of Labor Statistics, Consumer Price Index, September 1959.

Interestingly enough, the far more effective drugs of 1960 actually take less out of each individual's health dollar than they did 30 years ago. In 1930, 20 cents of each American dollar spent for health purposes went for drugs and sundries. In 1958, it was 19.9 cents—clear evidence that the price of drugs has not risen relative to the total expenditures for medical care.[32]

These drug prices, incidentally, account for about one penny of each person's disposable income. One cent for drugs. Compare that with the 5 cents of every dollar that goes for liquor and tobacco, or the 4 cents spent by the average American out of each dollar for entertainment.[34]

PRICE-CUTTING IN THE DRUG INDUSTRY

In view of the attention given to drug prices in this hearing, it would seem appropriate to emphasize the history of prices in this industry. The records show, as was pointed out in October 1958 Public Health Reports, that "prices of new drugs follow a characteristic pattern of decline after initial introduction, and when volume use and production takes place." [35]

These price decreases are the rule, not the exception. So much so that Professor Backman of New York University, whom I have cited earlier, has emphasized: "It is probable that if the full impact of the price declines for the newer forms of antibiotics as well as other new products could be measured, the average rise in all drug prices would be smaller than shown by the official indexes. Typically, when volume increases the prices of these products are cut sharply." [36]

I believe, for the record, you will be interested in some typical examples of this price-cutting activity in actual operation—taken from public sources as indicated.

By the spring of 1959, antibiotics, vitamins, and steroids were at the lowest price levels in history, having declined precipitously since they were introduced.[37]

The average price of antibiotics plummeted from $860 per pound in 1948 to a price last spring of about $160 per pound.[38]

After millions of doses of Salk vaccine were produced by industry in record time, the price was cut to only half its original level.[39]

The initial price of cortisone was $200 per gram. Several years later, it was $2 per gram.[40]

The price of penicillin in 1943 was $100 for 100,000 units. In 1946 it was $4.76. By 1956, the price was slightly over 22 cents.[41]

Streptomycin dropped 40 percent in less than a year.[42]

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[32] U.S. Department of Commerce, Survey of Current Business, various issues.
[34] Brush, Alvin G., op. cit.
[35] Kramer, Lucy M., op. cit.
[36] Backman, Jules, op. cit.
[37] McKeen, John E., op. cit.
[38] Survey of Current Business, May 1959.
[39] McKeen, John E., op. cit.
[40] Connor, John T., see note 19.
[41] U.S. Tariff Commission, "Synthetic Organic Chemicals," U.S. Production and Sales of Medicinals, 1956.
[42] Kramer, Lucy M., op. cit.

Insulin costs 6 percent of what it did 30 years ago, about the time it was introduced.[43]

These are, I want to stress again, not isolated examples. Downward movement of prices of new drugs usually occurs as sales and production increase and as competitive forces come into play.

As volume and distribution increase, prices decrease. As time passes, price competition from other manufacturers exerts a further downward pressure. And always the manufacturer lives with the risk, no matter how costly his early research, no matter how arduous and complex his development history, that his drug may at any moment be superseded by a far more effective medicinal—from his own laboratories, or from those of his competitors. These then are the sober facts about drug prices, in contrast to the sensational and misleading headlines we have been reading.

DISTRIBUTION OF THE CONSUMER DOLLAR

In view of the attention given in these hearings to the price of prescription drugs, I believe it may be helpful to put these costs in their proper perspective—and to cover, very briefly, the elements that go into a typical manufacturer's costs.

As you probably know, the average price of a prescription in the United States today is about $3. More than 60 percent of all prescriptions cost $3 or less. And only about one in 100 prescriptions costs as much as $10.[44]

The manufacturer, of course, receives only about 50 percent of the retail cost. The other 50 percent goes to the wholesaler and to the pharmacist, whose profit margins are traditionally modest.

This hearing is concerned with the manufacturer's price—the average $1.50 the producer receives for each filled prescription.

How does this $1.50 break down?

In most cases, in the drug field, the cost of raw materials is relatively slight—similar, for example, to the cost of wheat in a loaf of bread, or perhaps of cotton in a man's shirt.

The final producer's costs, however, must include factors such as production expenses, selling expenses, research, general and administrative expenses, taxes, licenses, royalties, reserves for depreciation, quality control and advertising and promotion.

As an example of the magnitude of some of these costs, take for example the problem of quality control—necessary to maintain purity and quality of drugs. One firm, in setting forth the control required for production of a corticosteroid, would need a roll of paper 1,000 feet long to put it on a single typewritten sheet.

(NOTE.—A detailed discussion of the drug industry's economics is contained in a separate report filed with the subcommittee.)

PATENT SYSTEM STIMULATES RESEARCH

Earlier in my testimony, I called attention to the intensity of competition in the field of research, and to the benefits gained by mankind from discoveries and products that have stemmed from this effort.

The role of the patent system, in providing incentives for investment of vast sums of money in endeavors which involve such great risks, is one which should be recognized by all who are concerned with the continuation of rapid discovery and the development of new medicines.

The interest of the American people lies in assuring that every feasible and practical means be devoted to the job of finding new answers to the mysteries of disease, to winning new victories in the war against sickness and death. In this, time is of the essence. A new drug discovered tomorrow is too late to save a life lost today.

PATENTS—A MAJOR INCENTIVE

The patent system works to provide incentive for the many companies, owned by hundreds of thousands of Americans who have invested their savings in drug concerns, to risk the enormous sums required in the gamble that one research project out of thousands will produce a result of benefit to mankind.

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[43] American Druggist, Blue Book, 1960.
[44] Market research department, Abbott Laboratories.

Obviously, the system affords no protection against the incredible risks of failure, against the loss of the millions of dollars that are spent on the thousands of research projects that fail.

But it does insure that any reward for research, for development, for contribution to society will go to those who have been willing to risk their savings and to devote their energies to this vital pursuit.

As you know, in the drug field these patents may cover products or the processes for manufacturing them. The original patent owner, of course, frequently licenses others to use it and receives royalty payments.

This assures, even in cases where substantial additional investments are required for final development, production, and distribution, that the drugs will be made rapidly available.

CROSS-LICENSING SPEEDS DRUG DISTRIBUTION

It also enables, in the case of cross-licensing, the prompt production of new drugs in cases where two or more firms may own patents which affect the production of a single drug.

The patent and licensing system has another advantage. It eliminates a situation in which so many companies would have the right to produce a drug that no single company would have the incentive to invest the sum required to move into production.

And this brings this discussion to a highly important point.

A new discovery alone will not cure a single living person of a single known disease. Even the production in quantity of effective medicinals will not affect a cure for one single person. No drug can accomplish anything until it is made available to the patient, until the Nation's doctors know what it can do and how it fits into the medical picture, and are assured it is available at the drugstore.

Thus, the drug industry's job is not done when the discovery is made and when the produtcion machinery is underway. It must devote equal zeal and energy to the task of distribution and education.

COMPETITIVE DISTRIBUTION SAVES LIVES

In this field, too, competition has produced another byproduct that has been a boon to the public. Distribution and advertising have enabled the private drug manufacturing industry to get new medicines to doctors and patients more rapidly than anywhere else in the world.

The educational and informational responsibilities of the prescription drug industry have no parallel in American enterprise. They are far greater than in any other industry, because they are inextricably tied up with life itself.

These responsibilities are carried forward with the communications tools of American free enterprise, including publications and direct mail advertising, and other effective devices for transmitting information where it is needed.

But even if we examine these practices solely as they relate to business competition, I find it paradoxical that on the one hand our industry is charged with being noncompetitive, while at the same time our advertising and promotion—use of time-tested American instruments of competition—are singled out for special criticism.

Our educational and promotional practices have a vital role in medical care and health and they have a vital business role. I want to examine both of these roles, beginning with how and why these practices came about in the first place and then developed to their present forms.

Studies show that 70 percent of today's prescriptions could not have been filled in 1935, and I have shown that since that date medical care has been revolutionized by drug discoveries. Dating approximately from the discovery of penicillin, the breakthroughs in effective prescription drugs have followed one upon the other at a rate unparalleled in medical history.

The ethical drug manufacturer's medical care responsibility has grown with commensurate speed. So great has been the change, in fact, that the prescription drug industry as we know it today is truly a new industry dating from the war.

With the quick succession of major breakthroughs during and after the war, and the onrush of thousands of effective new drugs, the industry faced an entirely new set of problems and resopnsibilities. Many of the new drugs were

actual cures, or in the case of the vaccines, preventives—not simply pain relievers as was so often the case before. Cures and preventives had to be brought quickly to the attention of doctors so that they could be used.

SLIGHT DRUG IMPROVEMENTS CAN SAVE LIVES

The critical importance of swift, comprehensive new product information is unique to the prescription drug industry. Even slight differences or product improvements can be important to the patients. Doctors are aware that unacceptable side effects may be produced in a patient treated with one form of a drug, but in some patients new or improved drugs frequently can reduce these side effects. In the infinite complexities of the human organism, the slightest change or improvement in a drug for a particular patient can mean the difference between health or illness, life or death. Prompt information about all such improvements is vital. Furthermore, since diseases respects few geographical boundaries, these drugs have to be continuously available nationwide, if they are to be of any value.

Thus, what was a comparatively leisurely business before the war—to a large extent concerned with restocking or improving existing items with an occasional new addition to the pharmacopoeia—suddenly was transformed by an explosion of discovery. As new drugs came one upon the other, new knowledge had to be brought continuously to physicians and pharmacists; and the new items had to be made continuously available.

Obviously, to maintain an acceptable level of medical familiarity with new pharmaceuticals, coupled with coast-to-coast availability of these new products, required national sales of sufficient magnitude to support these activities. Sales volume, in turn, was in direct proportion to the physician's and pharmacist's knowledge of the product and their ease of access to it.

I have given the name "competitive education and distribution" to the practices of the pharmaceutical industry which serve these three objectives—doctor education in new drugs, nationwide availability of new drugs, and a volume of sales sufficient to support the first two and to finance research that will lead to tomorrow's drug discoveries.

There are three principal tools of competitive education and distribution. Two of these, advertising and direct mail, are accepted practices of the free enterprise system—practices admirably suited to disseminating factual, objective information while they promote product use at the same time. The third tool, professional service representatives, or detail men, is unique to the drug industry.

DETAIL MEN INDISPENSABLE

Detailing is perhaps the most important of the three. Detail men form an indispensable link between the doctor and new knowledge that can help or save a patient. (See chart.)

Source: Attitudes of U. S. physicians toward the American Pharmaceutical Industry, opinion survey sponsored by the A.M.A., May 15, 1958

Survey after survey has shown that the detail man is the physician's first and most important source for new product data. In a poll of the Nation's doctors sponsored by the American Medical Association in 1958, 68 percent of the physicians interviewed stated that the detail man was the first source of information. Answering another question, 87 percent rated them as competent to very competent in their jobs. Many doctors also mentioned the detail man's proficiency as the touchstone of steadily increasing cooperation between the medical profession and the prescription drug industry.[45]

Similar findings were recently announced in a survey by Topics Publishing Co,[46] and in a scholarly paper entitled "The Detail man and Preference Behavior" by Dr. Norman G. Hawkins, assistant professor of preventive medicine at the University of Texas.[47]

[45] "Attitudes of U.S. Physicians Toward the American Pharmaceutical Industry," a survey sponsored by American Medical Association, May 1958.
[46] New Medical Materia, March 1959.
[47] Hawkins, G. Norman, "The Detailman and Preference Behavior," Mar. 27, 1959.

From the standpoint of both the physician and the pharmaceutical industry, the benefits of detailing are not matched by any other educational medium. In a few minutes the detail man can acquaint the doctor with the capacities and the limitations of a new drug. He can answer questions and frequently resolve lingering doubts.

DETAIL MEN HIGHLY TRAINED

Doctors are highly trained scientists who are not subject—and should not be subject—to commercial pressures. But they have high professional interest in ascertaining the value of new drugs and studying the circumstances under which they should be prescribed. The detail man is also a professional in his field. Most have college degrees in pharmacy or other sciences. All are thoroughly schooled by the companies they represent Throughout their careers they receive on-the-job training, followed up by rigid written examinations.

Doctor surveys have shown that medical journal advertising is the American physician's second chief source of new drug information, and in many ways this advertising complements and supplements the work of detail men.[48] Some doctors have already read new prescription drug advertising in medical journals before the detail man arrives, and can therefore devote the later face-to-face interviews to obtaining further information and close questioning on dosage, side effects, toxicity, and other technical aspects of the new product.

ADS TELL BAD AS WELL AS GOOD

Indeed, the word advertising is perhaps something of a misnomer when it applies to prescription drugs. Our so-called advertising is far different from the customary sales promotion message American consumers normally associate with the word. For the most part, our advertisements are more like scientific treatises, which differ from learned editorial comment in medical journals to the extent that we ourselves write these treatises and pay for the space where they are printed.

Ours are about the only ads in America that tell not merely the good things about our product, but deal exhaustively with the bad ones as well. Toxicity, side effects—all must be exposed in full detail. Some, of course, are "reminder" ads, intended to recall to the reader's memory the more extensive clinical findings he has seen earlier.

But the most important advantage of medical advertising is that it brings new product information to the doctors' attention almost as soon as the new drug has received approval by the Food and Drug Administration. This is not true of scholarly articles which appear in the editorial content of medical journals. The time lag here ranges between 6 months and a year.

TIME LAG WOULD BE INTOLERABLE

Any time lag between the approval of a new product and the doctor's knowledge of that product is, of course, intolerable where health and often life itself are at stake. Advertising, supported by detailing, is the fastest means our free enterprise system has produced to guarantee that the lag between availability of a drug product and its use in treatment is held to a minimum.

The proved efficiency of advertising, detailing and direct mail are all the more vital when you consider that effective new drugs are being added to the pharmacopoeia at an average rate of about 40 each year.[49]

These educational devices take on added importance when one considers that more than half of today's doctors graduated from medical school prior to the medical revolution in chemotherapy. Even recent graduates, given the present rate of pharmacological discovery, soon find areas of their academic training in chemotherapy made obsolete by the steady procession of new and better prescription drugs.

MANY MAJOR AIDS TO MEDICAL PRACTICE

The ethical drug industry makes many other contributions to medical knowledge in the public interest. Such contributions are often and, I believe, wrongfully categorized as advertising or promotion.

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[48] AMA, op. cit.
[49] PMA, op. cit.

Educational funds support a large part of most medical society programs through journal advertising and exhibit space.

They contribute substantially to the economic existence of most medical journals. The ethical drug industry's contribution last year is estimated at about $41 million to support approximately 1,600 issues each year of general medical, scientific and surgical journals, plus a possible 1,000 issues of about 190 local, State and regional journals.

They provide amost all available closed-circuit educationa TV for physicians.

They provide a large part of the available medical teaching films. About 39 companies have substantial film programs.

They provide for the circulation of reprints, abstracts and reviews of medical reports printed by medical editors.

They provide a substantial number of medical seminars each year.

These funds also finance millions of samples used by doctors to determine their patients' response to a drug before the patient spends money to fill a prescription—a vital medical function benefiting patient and doctor both.

As a point of terminology worth mentioning at this stage, whether we label these categories of expense educational, informational or promotional makes little practical difference. For in fact these expenditures do all three. The demands for swift, thorough information to doctors and pharmacists; the demands for continuous, nationwide availability of our products; and the demands of our industry for a sufficient volume of sales to prosper and expand are completely interdependent. None of these essentials—education, nationwide availability, or sales could possibly exist without the other two.

Fundamental to the successful system of education and distribution is the industry practice of using brand names rather than the generic names of its formulations. There are compelling reasons for this practice.

BRAND NAMES VITAL

First, and most obvious, is a fact indigenous to the American enterprise system. Unless a manufacturing industry gives a name to its products, it cannot hope to meet competition and maintain its sales, let alone to improve them. Like other industries, each member company of the ethical drug industry strives to excell in its products and to make them known so that they will be brought and a coast-to-coast inventory can be maintained. The only way for a company to make them known is to give them a name different from its competitor's.

Brand name identification is particularly vital for the innovating companies which account for the majority of new drug advances. These innovating companies take the initial risk of enormous marketing investments to make their new drugs available—on the shelves—in the drugstores of the Nation, and always with the possibility that the new product may fail through some unforeseen circumstance.

The innovating firm's only protection in maintaining the market it has developed, and its only basis for anticipating sufficient sales to cover the costs that made the drug possible and available in the first place, is the confidence and trust physicians associate with the company's brand name.

BRAND NAMES PROTECT PATIENT

Behind brand names lie the reputation, reliability, and skill of the manufacturer.

By brand name prescription, too, the doctor orders for a patient a specific product in which he has absolute knowledge of quality, purity, and any side effects that might have importance for a particular patient. In the case of combination formulations, brand names stand not only for the active ingredients, but also for special excipients, vehicles, and bases, frequently developed by costly research to be nonallergenic, specially buffered to promote tolerance, sugar-free for the obese and diabetic, and many other important variations for individual patient needs. So-called generic equivalents often do not.

A system allowing pharmacists to substitute generic equivalents for brand name prescriptions is tantamount to restricting the physician's choice and authority, and transferring some of his decisions to the pharmacist. I scarcely think the American people would welcome this.

From the standpoint of the physician and pharmacist, the use of generic equivalents would in no way lessen, but might well increase, their liability, because it could increase the chances for unfavorable reactions to the detriment of the patient. Under the American system of medical care, the physician alone arrives at the diagnosis and he alone should decide precisely what drug is to be prescribed for his patient. This is a vital part of the physician's responsibility in medical care and it is his responsibility alone.

A generic drug, as you know, is required only to meet the standards of the U.S. Pharmacopœia, which is published every 5 years, or the National Formulary, which is published at irregular intervals. These list drugs only by generic names and often lag far behind brand name drugs in actual usage. The Salk polio vaccine which has been administered to millions is not yet listed in either publication.

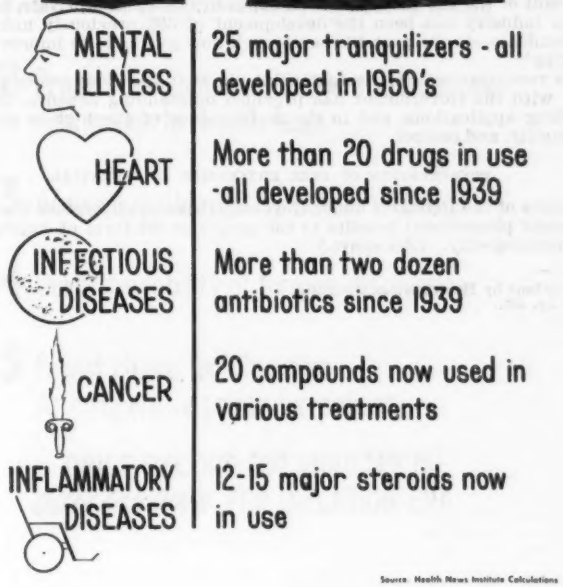
Thus the issue resolves itself to a question. Should seriously ill patients be deprived of the benefits of new drugs developed by manufacturers at their own expense until such time as the formula is available to any drug compounder who cares to use it?

I have tried to sketch for you the basic ingredients of the system I have called competitive education and distribution, and to explain why it is an indispensable boon to the medical profession, to 180 million real or potential American patients, and to the existence and future progress of the pharmaceutical industry in their behalf. It is, in short, a system that insures that the right drug will be available at the right place and at the right time; that it will be prescribed by a physician who knows about it, trusts it, and knows how to use it; and that it will be dispensed by a highly trained, professional pharmacist. The most expensive drug in the world is the one that is not available where and when it is desperately needed.

THE MOST IMPORTANT MEASURE: VICTORY AGAINST DISEASE

The most important measure of the contributions of this industry is in the answer to the question: Has the functioning of the drug industry under the competitive free enterprise system provided the best possible means of making available new discoveries and improved medicines to the greatest numbers of people? (See chart.)

Industry Develops Effective Drugs for Major "Killer" and Crippling Diseases


DISEASE
DRUGS DEVELOPED
MENTAL ILLNESS
25 major tranquilizers - all developed in 1950's
HEART
More than 20 drugs in use -all developed since 1939
INFECTIOUS DISEASES
More than two dozen antibiotics since 1939
CANCER
20 compounds now used in various treatments
INFLAMMATORY DISEASES
12-15 major steroids now in use

Source: Health News Institute Calculations

The answer, I submit, is clear.

America's private drug industry can demonstrate a record of service unparalleled in modern history. A quick look at the list of effective drugs developed for use against major killing and crippling diseases shows:

Twenty-five major tranquilizers, all developed in the 1950's, now being used to combat mental illness.

More than 30 drugs, developed since 1939, in use against heart disease.

More than two dozen antibiotics, developed since 1939, fighting infectious diseases.

Twenty compounds now being used in various treatments of cancer—and unremitting laboratory research in efforts to create the long-sought drugs that will help eliminate the ravages of this scourge of man.

Twelve to fifteen major steroids now in use against inflammatory diseases.[50]

The result of the enormous research expenditures by this private, enterprising American industry has been the development of 392 previously unknown medicinal chemicals—in the past 10 years—each now available to improve health or reduce pain.[51]

In this race, this search, I might point out that the close cooperation of the industry with the Government has provided outstanding benefits—in research, in new drug applications, and in the maintenance of the highest standards of purity, quality, and control.

PRESERVATION OF FREE ENTERPRISE IS ESSENTIAL

Operations of the industry, under the competitive profit system we now enjoy, have brought phenomenal benefits to the people in the form of improved health and greater longevity. (See chart.)

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[50] Calculations by Health News Institute.
[51] PMA, op. cit.

Public Benefits of the Competitive Profit System in DRUGS

1 Best incentives for developing needed drugs

2 Prompt distribution of drugs and treatment information to Health Team

3 Assured quality, purity, safety of Drugs

4 Quick availability of foreign discoveries

5 Freest choice for physician -
At competitive prices for patient

PRICE RECORD FOR INDUSTRY IS
OUTSTANDING FOR INFLATION ERA

This system has similarly brought a new element of strength to the national economy by the development of a sizable industry, characterized by stable employment and a dynamic technology. The pharmaceutical manufacturing industry is a good customer of other industries and thus a big contributor to the Nation's prosperity.

Every level of government has benefited because of local, State and Federal taxes generated not only by the manufacturing companies but by the suppliers, wholesalers, retailers, employees, and shareholders partially or fully dependent upon the industry for income.

The leadership of the American industry in the development, production, and distribution of revolutionary new drugs has enhanced the prestige of the United States throughout the free world. Improved health standards brought about by American-developed drugs have been even more dramatic in some other areas of the free world than in this country. This speaks well for the democratic free enterprise system at a time when the United States is embattled in a war of ideologies.

The alternative to competitive free enterprise in the drug industry is Government regulation and controls which will destroy the incentives that have produced the great contributions of the drug manufacturing industry.

Where government controls have been imposed on drug manufacturers abroad, or where government has interfered with or hampered the operation of a free manufacturing industry, progress in the development of new drugs has been stifled. There is no reason to expect a different result here.

THE FREE VERSUS THE CAPTIVE INDUSTRY

Throughout the world the American drug manufacturing industry is credited with much of the improvement in health of the past few decades. The famous Hinchliffe report to the British Ministry of Health said that following the discovery of streptomycin in 1944 by Waksman, "all subsequent antibiotics have been discovered by scientists working in the laboratories of pharmaceutical firms, almost all in the U.S.A." The same report pays tribute to industry in the development of the sulphonamides, penicillin, and the corticosteroids.[52]

Dr. A. Lawrence Abel, senior surgeon to the Royal Marsden Hospital and Institute of Cancer Research in England, has said that only 7 of the 24 United Kingdom companies specializing in ethicals are British owned. "The American invasion springs from the great depth of activity, willingness to take risks, and freedom over financial controls of the U.S. pharmaceutical industry." [53]

In Austria, state control over every aspect of medicine and medical services has discouraged the formulation of a significant drug manufacturing industry. Practically all drugs are imported.

Evidence adduced from industry witnesses during earlier sessions of this hearing make it clear that the American industry produces drugs in many countries throughout the world and export to most of the others. This is prima facie evidence of the great world wide demand for American drugs.

Perhaps the most striking proof of America's phenomenal progress comes from the Soviet Union, whose eminence in science and technology is a matter of some concern. Not a single new compound of any significance has come out of Russian laboratories since the October revolution 42 years ago. However, American companies are receiving some of their most difficult competition in foreign markets from Russian drugs pirated from American formulas.

It can hardly be disputed that the American pharmaceutical manufacturing industry, operated under the incentives of a free economy, has brought to the corner drugstore in the postwar era more drugs and more effective drugs than in all the preceding centuries.

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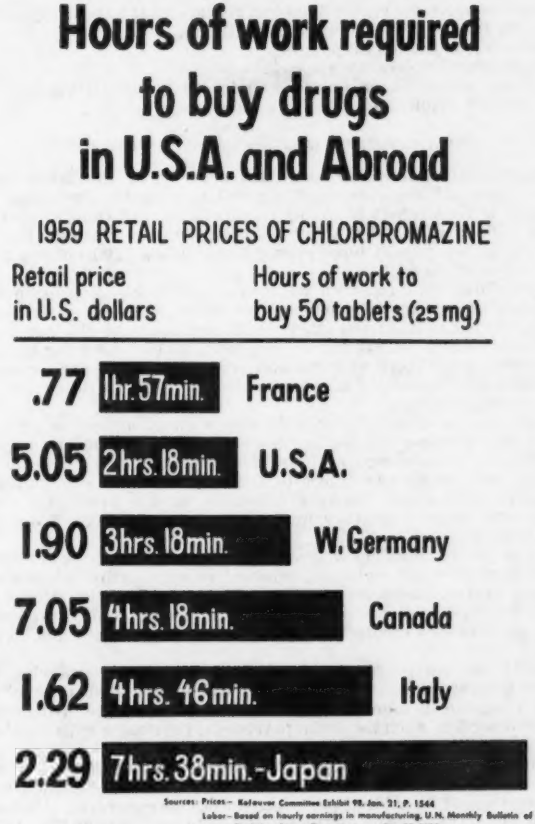
[52] Hinchliffe, op. cit.
[53] Abel, A. Lawrence, in an address, New York, Dec. 9, 1959.

DRUGS ARE A BARGAIN IN UNITED STATES

This committee has reviewed variations in price for pharmaceuticals between the United States and selected other countries. Based on price figures contained in the record and on average hourly wages from reputable sources, I have prepared the following chart which demonstrates the American workers put in fewer hours of labor to earn money with which to purchase these drugs.[84] (See chart.)



[84] Prices—Kefauver Exhibit No. 98, Jan. 21, 1960, p. 1544. Labor—based on hourly earnings in manufacturing reported in U.N. Monthly Bulletin; for Japan, Time magazine, Dec. 28, 1959.

I can think of no more pointed evidence to prove that free enterprise is providing a bargain in medicine for Americans. Since this is patently so, it is not in the interest of the public to abandon the system that has made it possible.

The choice before us is clear cut:

To maintain a competitive health team that has scored phenomenal progress:

Doctors, pharmacists, universities, hospitals, manufacturers, all in active competition to make improvements;

Team closely cooperating with government health institutions;

Industry, druggists, doctors, employees paying taxes; or

To impose bureaucratic regulations and redtape that have everywhere:

Limited free choice of doctors and patients.

Increased burdens on taxpayers.

Slowed down life-saving research.

Required subsidies or public salaries to many members of the health team, plus obnoxious and expensive redtape.

HEALTH PROGRESS WILL ACCELERATE IN THE FUTURE

The pharmaceutical industry is an embodiment of the truth stated in the motto on the National Archives building: "What Is Past Is Prologue."

The nature of research is to amplify knowledge and thus to open new doors to progress. It is estimated that by 1970 the present expenditures on research by drug manufacturers will have grown from 1959's $200 million to the neighborhood of $400 to $500 million.

The record shows that research within our children's generation has changed the complexion of our health problems by wiping out some diseases, by cutting much of the hazard to life from others, and by increasing the average life span.

New discoveries and developments have been accelerating for the very reason that the growing abundance of basic and applied research are, as somebody has said, "teaching us the extent of our ignorance," and in doing so, opening up new avenues of exploration.

It is reasonable to expect that the intensive effort and growing expenditures for research will produce results in the next 10 years at least comparable with those of the past decade, and perhaps more spectacular. Some of the health problems that are presently subject to industry research are indicated below:

Cardiovascular-renal diseases (diseases of the circulatory system and kidney) and cancer together accounted for more than 7 out of each 10 deaths in 1957.

Little is yet known about neurological disorders such as cerebral vascular disease, Parkinsonism, epilepsy, cerebral palsy, multiple sclerosis, muscular dystrophy and similar disorders that afflict some 5 million of our population.

Viral and bacterial diseases such as influenza, colds, staphylococcus infections and others create widespread misery and have not yet been conquered.

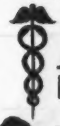
Some 17 million people in the United States are suffering from some form of mental illness. While the psychotropic drugs have proved extremely valuable in increasing the cure rate, there are still no basic cures for some disorders such as senile psychoses, psychoses with cerebral arteriosclerosis, alcoholism and others.

Although the corticosteroids have proved effective for some serious eye diseases, glaucoma and cataracts are still blinding many men and women. Nearly one out of four blind persons over 60 has cataracts. Glaucoma is the cause of about 14 percent of the blindness in people over 35. (See charts.)

Composition of America's *Health Team*

DRUG MANUFACTURERS
1,000 COMPANIES 100,000 EMPLOYEES

DOCTORS
239,000



DENTISTS
100,534

MEDICAL TECHNOLOGISTS
88,211

NURSES
277,000

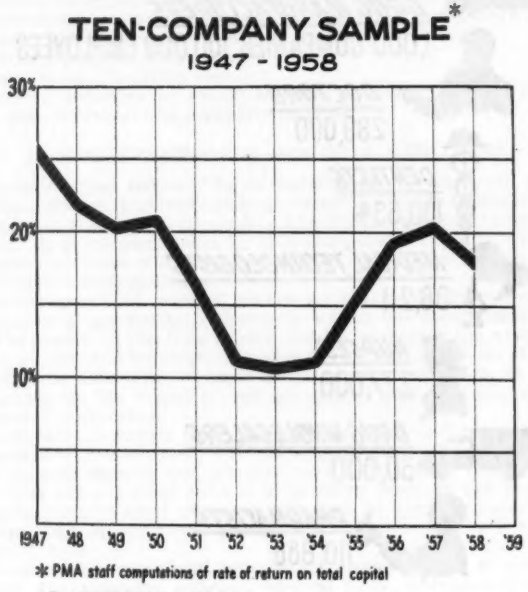
DRUG WHOLESALERS
30,000

PHARMACISTS
110,868

... AND OTHERS.

Source: PMA Staff Compilation

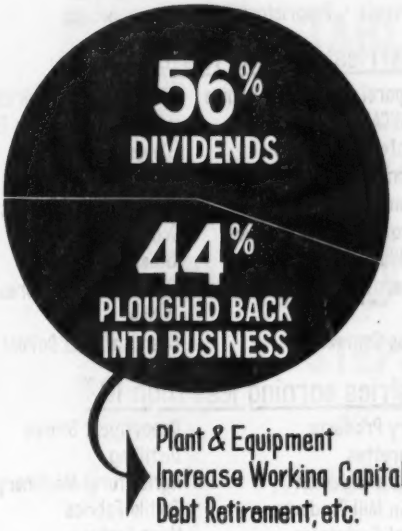
Trend of
Drug Industry Earnings



* PMA staff computations of rate of return on total capital

What Happens to Drug Industry Profits?

Six Company Sample 1958



Source: PMA Staff Computations

Comparative Industry Earnings Rates 1953-57 *

STANFORD RESEARCH INSTITUTE

Industries Earning 15% and Over

Aircraft · Proprietary Drugs · Automobiles

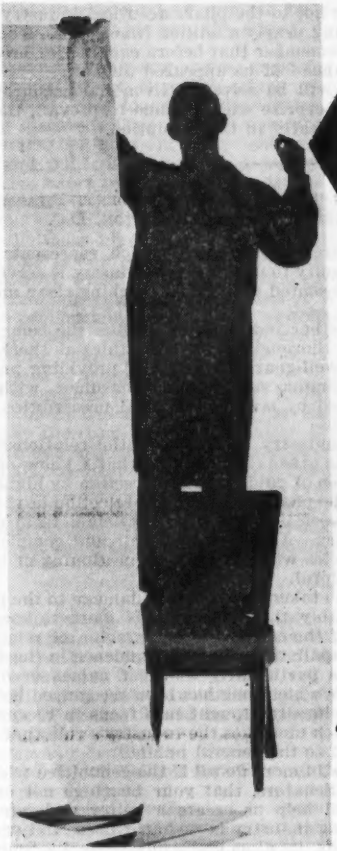
Industries earning 10% to 15%

Apparel & Accessory Chains
ETHICAL DRUGS
Nonferrous Metals
Corn Products
Chemical (incl. Du Pont)
Auto Parts & Accessories
Building Materials
General Industrial Machinery
Oil
Glass Containers
Toilet preparations & Soap
Electrical Supplies & Equip.
Copper
Packaged Foods
Paper & Allied Products
Mail Order Houses
Steel
Grocery Chain Stores
Rubber
Chemical (excl. Du Pont)

Industries earning less than 10%

Dairy Products
Cigarettes
Radio & Television
Grain Mill Products
Metal Containers
Limited-Price Variety
Department Stores
Distilling
Agricultural Machinery
Textile Fabrics
Meat Packing

*On total capital


THIS
TINY
TABLET
required
1200
STEPS
in
manufacture

These are staggering challenges not to the pharmaceutical industry alone but to the entire health team numbering nearly a million Americans. Yet, when we look back through the years, we remember that before each major breakthrough in medicine the challenges then ahead of us appeared difficult.

The problems ahead of us too will be solved. Given the encouragement to proceed in confidence that free enterprise will continue to prevail, the pharmaceutical industry can contribute greatly in their solution.

PART II. STATEMENT OF AUSTIN SMITH, M.D., PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.

The Pharmaceutical Manufacturers Association, which represents 140 companies, is grateful for this opportunity to describe the industry it serves, and we hope that the information here presented will aid in reaching clear understanding and sound conclusions.

So far as I know, there is no other industry into which the committee has inquired in which there is such a thoroughly accepted ethics as there is in our industry. There is an unusually well-guarded system of providing professional guidance for manufacturer, distributor, retailer, and consumer, with the consumer's right to purchase restricted by law to a medical prescription which is personal, private, and confidential.

In fact, to my knowledge this industry is unique in the relationship it has with the ultimate consumer. In no other circumstance that I know of does the consumer enjoy a comparable degree of guidance and direction by highly trained professionals—the physician and the pharmacist—in the selection of the product.

Not only as head of a trade association but as a physician, I am deeply interested in this committee's inquiry. I believe that full and complete understanding of our practices and policies will assist your questioning of individual companies, and I am here to be helpful.

I also feel that great care must be taken to avoid any damage to the physician-patient relationship. Unquestionably the committee is alert to this hazard, and realizes that discussion here of the composition, character, or relative value of specifically named drugs may impair the patient's confidence in the treatment prescribed by his doctor. This is particularly likely if names of drugs and diseases are linked. It is a danger which long has been recognized both in and out of Congress, and has been specifically brought into focus in recent congressional inquiries. It is a danger which underlies the industry's rule that prescription drugs are not to be advertised to the general public.

I would be pleased to discuss this in more detail if the committee wishes.

We believe, Mr. Chairman and Senators, that your hearings not only could serve the public interest but could help us create a better understanding of what the ethical drug manufacturing industry is—what it does, and why—what it does not do, and why—its methods, its aims and aspirations, its contributions to the better life. The pharmaceutical industry's major task is to provide an abundant supply of safe, effective prescription drugs and to discover, screen, develop, and make available new drugs which will decrease and end suffering, and promote longer and happier lives, and to manage to stay in business while it is so doing.

Everyone is vitally interested in his own and his family's well-being The extent and depth of this avid curiosity and interest in medicines and drugs grow day by day; newspapers run regular columns on health hints and medical discoveries, some periodicals feature, often flamboyantly, new therapeutic techniques and medicines. Almost all of our popular weekly magazines have a section devoted to medicine; one of the editors of the Saturday Evening Post recently reported that whereas his magazine published only 2 articles dealing with health and medicine in 1936, the count had risen to 36 for 1956.

Many physicians can relate disturbing experiences with patients who have been impressed by this avalanche of popularized medicine. Every so often, an unhappy patient, or his relatives, tries to persuade his doctor to give him a prescription for "the latest drug"—perhaps one only under preliminary investigation, or even nonexistent—which he has read about. In other instances, because he places his own interpretation on clinical aspects better suited to a medical audience than to the public, a patient may resist medication even though for him the best medical judgment regards it as particularly suitable.

Against this background of reliance by doctors on the safety and efficacy of drugs available for his use, the ethical drug industry's work is carried out in several major areas.

First, research—the never-ending quest for new drugs. The industry brings together specialists of literally scores of different scientific fields in well equipped laboratories to devote their time to the discovery of new means of conquering disease. They explore new areas of chemistry, try new uses for old compounds, test substance after substance for possible medicinal use. This has been and will continue to be a highly organized, dedicated, and remarkably effective effort to discover new drugs. The success of the U.S. industry is without parallel.

It is often a long step from the identification of a therapeutically useful substance to the mass production of a drug which makes it available to all who need it. This is the second principal area of activity—the development and production work which carries a substance forward from a laboratory curiosity to a medicine available for prescription by a physician. The solution of these production problems is often at least as difficult as the research which preceded it. Pharmaceutical formulation of the medicinal chemical in a stable form and of consistently high quality suitable for administration to thousands is an important area of activity.

The third problem is to bring exact knowledge of the newly developed pharmaceutical or biological product to the attention of some 200,000 physicians, and to make the drug itself immediately available on their prescription. This is done through a vast communication effort which includes reports in scientific journals, medical symposia, advertising, detailing, sampling; the use of all modern communication techniques to carry accurate information on the drug to the physician as quickly as possible There must also be established an effective distribution system to make the drug available promptly to the patient at the moment and place his physician requires.

THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

The Pharmecutical Manfacturers Association is successor to two other national associations in the same field, the American Drug Manufacturers Association and the American Pharmaceutical Manufacturers' Association.

It is a voluntary, nonprofit professional and trade group, composed of 140 manufacturing members, principally engaged in the production of what are often called "ethical" drugs. These are pharmaceutical products primarily advertised to physicians and usually restricted to sale only when prescribed or recommended by a physician or dentist and dispensed by a licensed pharmacist.

Among the objectives and activities of the association are four which may be of particular interest:

First, the association endeavors to encourage consistently high standards of potency, quality, and purity for pharmaceutical and biological products intended for use by the medical and allied professions in the cure, mitigation, treatment, prevention, or diagnosis of disease. In this area, the Pharmaceutical Manufacturers Association works with appropriate governmental agencies in the establishment of the necessary scientific and technical standards for ethical prescription drugs.

Second, the association encourages research in the development of new and better medical products, and better facilities and methods for the pharmacological and clinical evaluation of them, and safe methods of manufacture, packaging, and transportation of these vital drugs. The association and its predecessors have a splendid record for supporting uniform and reasonable drug legislation for the protection of public health, and also a fine record of cooperation with the Food and Drug Administration, the Public Health Service, and other regulatory bodies in the proper enforcement of such legislation.

Third, the association disseminates information both on governmental regulations and policies and on other subjects of interest to the industry it serves. In addition, the association has done a great deal to encourage development of scientific and technical skills necessary to the discovery, evaluation, and production of pharmaceutical and biological products.

Fourth, on a very broad front, the association through its many technical committee works constantly and closely with other professional associations or groups in the health field, with allied industries, and with Government authorities, for the advancement of medical science.

Because of the great emphasis within the association upon technical matters, it is often regarded primarily as a scientific society, operating within areas devoted to the public health and well-being. These scientific activities are largely carried out by 5 specialized sections, which operate through some 50 committees. The sections are composed of biologists, chemists, pharmacologists, physiologists, physicists, pharmacists, physicians, veterinarians, engineers, statisticians, research administrators, and scientific literature specialists. To cite just a few examples, their committees study problems of drug analyses, clinical drug evaluation, blood dyscrasias, toxicology, plant maintenance, efficient packaging and production methods, microbiological assays, spectrography, maintenance of sanitary conditions, sterilization, materials handling and aspectic procedures.

In addition to the five scientific sections referred to above, there are five other sections within the association. The functions and makeup of the 10 sections may be summarized as follows:

Biological.—Composed of biologists, biochemists, veterinarians, pharmacologists, and other scientists in related fields. Concerned with technical problems related to products licensed by the National Institutes of Health and the Agricultural Research Service and technical problems involving other biological products. Sterility tests, pyrogen standards, biological standards; blood products and deriavtives; microbiological and pharmacological assays; biological manufacturing problems of general interest; liaison with NIH and ARS.

Financial.—Composed of controllers, accountants, treasurers, and other fiscal specialists, and devoted to the study of accounting and costing methods; Federal and State taxation, taxation of foreign business; statistical methods; inventory control; functional relationships of the accounting department with other company departments.

International.—Composed of administrators, lawyers, financial, technical, and personnel experts interested in the oversea operations of Pharmaceutical Manufacturers Association member firms. The international section has grown into a miniature counterpart of the association itself, with committees studying specific technical areas related to the field of activity of other Pharmaceutical Manufacturers Association sections.

Legislative.—Composed of attorneys, administrators, and patent specialists, and concerned with general legal problems of the association, its officers, sections, and committees; regulations and procedures of Federal, State, and municipal agencies; foreign law problems; legal aspects of drug labeling; patent and trademark problems of general interest; Federal and State legislation; legal aspects of taxation.

Medical.—Restricted to physicians, although other representatives of member firms can attend meetings as observers; devoted to clinical research problems of general interest; medical department administration; relationships of company medical department with other departments; relationships of the drug industry with professional societies; medical aspects of the governmental evaluation of new drugs; medical manpower problems; specific clinical and pharmacological resesrch projects supported by the association.

Pharmaceutical contact.—Composed of chemists, pharmacists, and other scientists working on drug standards, and devoted to cooperation with the Food and Drug Administration, the U.S. Pharmacopeia, the National Formulary, and other groups in developing standards and methods of assay for nonbiological pharmaceutical products; quality control procedures; maintenance of sanitary conditions; quality control administration; relationship of the quality control department with other company departments.

Production and engineering.—Composed of administrators, engineers, and plant superintendents, and involved with production, plant engineering, maintenance, packaging, safety, and allied problems; relationship of the production department with other company departments; inventory and production control; production manpower problems; materials handling; automation; plant expansion problems; production equipment; special production techniques.

Public relations.—Composed of administrators and specialists concerned with public education. The section concerns itself with general public relations problems, publicity, and similar matters.

Research and development.—Composed of research administrators, chemists, pharmacists, pharmacologists, biologists, physical chemists, and other scientists whose primary interests are in the research field. Problems studied include administration of the research department, and its relationships with other company departments; scientific manpower problems; pharmaceutical applications

of physical chemistry techniques; physical chemistry laboratory equipment; distribution of physical chemistry data; organic and biological chemistry problems of general interest; the scientific literature; indexing and retrieval of information; pharmaceutical development problems of general interest; new materials and techniques in pharmaceutical development; contact with governmental research groups, particularly at the National Institutes of Health and the National Research Council; research and pharmacological problems connected with the governmental evaluation of new drugs; animal testing and screening techniques.

Transportation.—Composed of traffic and transportation specialists and other experts in distribution, and primarily concerned with common carrier rates on drug products; Federal and State transportation regulations; pharmaceutical industry representation in rate proceedings; problems related to small shipments; cooperation with Drug and Toilet Preparation Traffic Conference and National Small Shipments Traffic Conference.

It is important for the record to show that the Pharmaceutical Manufacturers Association does not, in any way, concern itself with distribution or sales policies of its member companies. It has nothing to do with distribution methods or with prices.

Further, it is not a lobbying or propaganda organization. Within lawful limits its principal role is that of responsible leadership for the pharmaceutical industry.

Among the Pharmaceutical Manufacturers Association committees and task forces are the following, although new committees from time to time are added and older committees are combined:

Committees of the board of directors:
- Nominating.
- Membership.
- Government-industry.
- Professional relations.
- Public relations.
- U.S.P. policy.

Committees of the association:
- Taxation.
- Nonbiological veterinary products.
- Annual Pharmaceutical Manufacturers Association Award Board.
- Annual meeting entertainment.

Other regular appointments by board chairman:
- Assignment of region to each vice president.
- Appointment of section chairmen.
- Appointment of board members as liaison representatives to sections.
- Appointment of delegates to national drug trade conference.

TASK FORCE ON CANCER STUDY

Committees of the Biological section:
- Blood and blood derivatives.
- Control testing.
- Stability studies.
- Poliomyelitis vaccine.
- Veterinary products.
- Publication of section records.
- Planning.
- Virus products.
- Mandatory and international standards.
- Microbiological assays.
- Pharmacological assays.
- Special technics.

Committees of the financial section:
- Integrated data processing.
- Tax.

Committees of the international section:
- Administration.
- Financial.
- Legal.
- Personnel.
- Public relations.
- Technical.

Committees of the legislative section:
- Animal feed additives.
- Color additives.
- Karsten bill.
- Medico-legal problems.
- Patent and trademark.
- State legislation.
- Warning statements (FDA).
- Tax.

Committees of the medical section:
- Blood dyscrasias.
- Cardiovascular diseases.
- Drug addiction and habituation.
- Hospital staphylococcal infections.
- Liaison with AMA Council on Scientific Assembly.
- Medico-legal problems (liaison with legislative section).
- Medical writing practices.
- Medical careers in the pharmaceutical industry.
- New drug applications.
- Nominating.
- Poison control centers.
- Professional relationships.
- Psychotherapeutic drugs.
- Training for clinical research.
- Warning statements (FDA).
- Project.

Committees of the pharmaceutical contact section:
- Tablet disintegration.
- Tablets and capsules, timed release.
- Buccal tablets, tests.
- Biological filters.
- Drying methods in U.S.P. and N.F.
- Medicated feeds.
- Folic acid assay.
- Certified colors.
- Rubber closures.
- Nitroglycerin tablets assay.
- Cascara and emodin bearing drugs, assay.
- Quality control administration.

Committees of the production and engineering section: None.

Committees of the public relations section:
- Government relations.
- Professional relations.
- Press relations
- Publications and other media.
- Special projects.

Committees of the research and development section:
- Pharmaceutical development.
- Physical-analytical.
- Organic-biochemistry-pharmacology.
- Pharmaceutical literature.
- Research administration.

Committee of the transportation section: Shipment of etiologic agents.

GROWTH AND DEVELOPMENT

The first pharmaceutical manufacturing laboratory in the United States was established in 1778 at Carlisle, Pa. It supplied medicines to George Washington's army. If indeed the industry can be said to date from that early time, it should be further noted that for most of these two centuries its importance was small and its contribution to medical care bordered on the unimportant. In fact, the industry remained an infant until the period following World War I and certainly did not progress beyond adolescence until the beginning of World War II. Sales figures for the industry confirm this point. As recently as 20 years ago, in 1939, total sales volume was only $149 million. In 1958, the market for ethical pharmaceuticals was in the neighborhood of $2 billion at manufacturers' prices.

Why did the pharmaceutical industry take so long to find its stride? How did the industry get where it is today? There is no single reason, but by far the most important is the development of modern medical science which could be utilized by the pharmaceutical industry; 20 years ago the drug industry's expenditures for scientific research and development were estimated to have been approximately $15 million—last year they were in the area of $190 million. The success of these efforts has effected a revolutionary change not only in drug manufacturing but in the practice of medicine itself. In this respect, it might be pointed out again, unlike what a few critics have said, that most of the major drug discoveries of the past two decades have been made in the United States of America and by U.S. firms either in their laboratories or in laboratories elsewhere in which the work was supported by U.S. firms.

THE MAKE-UP OF THE INDUSTRY

The Census of Manufactures for 1954 showed 1,163 pharmaceutical manufacturers employing 76,585 employees, having a payroll of $353,768,000, and a value of shipment totaling $1,643,140,000. These employment figures exclude the sales force of the "ethical" companies. Of these companies, 724 had between 1 and 9 employees; 327 had between 10 and 99 employees; and 112 had over 100 employees. Leading States in the manufacture of pharmaceutical products were New York, New Jersey, Indiana, Michigan, and Illinois. Hourly earnings for production workers and nonsupervision people almost doubled in the 10 years 1947–57, while hours worked remained constant.

The manufacture of biological products is a specialized operation by manufacturers who produce vaccines, serums, toxoids, and analogous products such as allergenic extracts, normal blood serums, and blood plasma for human or veterinary use. There are nearly a hundred such manufacturers concentrated primarily in California, Indiana, Nebraska, Kansas, Michigan, Pennsylvania, and New Jersey.

Prescription drugs

Traditionally, a prescription drug (sometimes called ethical drug) is one that is promoted to practitioners such as doctors and dentists and to pharmacists, not to the general public. Promotion of drugs for the professions is a matter of educational information; that is, of providing the health professions with knowledge of the drugs' availability, usefulness, and potential harmful side effects in treating patients.

Proprietary drugs

A proprietary drug is one which is advertised, usually by mass media, directly to the consumer. Proprietaries in general are home remedies for the relief of minor, temporary ailments, and which can be bought without a prescription.

Since 1939 the pharmaceutical industry has seen a tremendous change in the proportion of drugs classed as ethicals as compared to those sold as proprietaries.

In 1939 the estimated total "ethical" drug sales at manufacturers' level was $149 million, while proprietary sales were estimated at $152 million.

Last year ethical sales reached as much as, or close to, an estimated $2 billion while proprietary sales had advanced to $700 million. This reflects the chemical revolution in medicine since World War II.

PRODUCT ANALYSIS

The primary classifications into which the products of the ethical pharmaceutical industry fall at the present time are as follows (figures cited here represent U.S. volume only, calculated at the manufacturers' level):

Antibiotics.—Some of the diseases most devastating to man are those called infections. Pneumonia, meningitis, typhoid fever, "childbirth fever," and "blood poisoning," if one can be permitted to include popular terminology, are examples. Thirty years ago at least a third of those who developed pneumonia died. Today the percentage is minimal. And so it is for other infections susceptible to antibiotic therapy. But large amounts of such drugs are necessary to meet medical demands.

This group of anti-infective agents accounts for a total annual volume of $255 million, and is the single largest product group in the industry. It is relatively new, since the first antibiotic, penicillin, became generally available only during World War II. Major categories within the antibiotics group are the broad and medium spectrum products, which account for 68 percent of the total, and the various forms of penicillin, which account for 18 percent of the total.

Vitamins and minerals.—Years ago one of the most baffling and discouraging problems involved malnutrition. Physical wasting, nervous manifestations, skin disorders, visual disturbances, and improper functioning of the stomach and intestines were just a few of the many complaints due to lack of vitamins. Medical science forged ahead for the benefit of all mankind when it solved the mysteries of poor nutrition.

This is the second largest product group, aggregating $160 million per year. Included in this category is a broad range of single-vitamin products and multivitamin compounds which are formulated by individual companies and marketed as specialty products under trade names. Most products have distinctive individual characteristics and are designed to fill specific needs. It should be noted that tihs product category does not include the production of synthetic vitamin powders in bulk by chemical producers. Bulk vitamin powders are not considered to be in the specialty pharmaceutical area. The bulk producers sell these basic vitamins to other manufacturers in the industry who in turn use them as ingredients in the indivdual formulations noted previously.

Hormones.—Another area of medicine which offers many perplexing problems in concerned with the glands of the body. Young and old, male and female, experience glandular dysfunctions. While many tragedies have developed because of the lack of adequate drug therapy in the past, today most of the disorders can be brought under control. Well known to all are such problems as diabetes and the menopause, or "change of life."

This significant product group, which has emerged as a category of major importance in only the last 10 years, represents a total annual volume of $120 million. Major subcategory is the corticoids, representing 75 percent of the total. Others are estrogens, androgens, and progestogens. The corticoid group is the most recent and most dramatic area of scientific and commercial breakthrough. A particularly notable field of use for these products has been in the treatment of arthritis and rheumatism.

Analgesics.—One does not need to have an operation to experience pain. An aching tooth, a headache, a pain in a muscle can be just as provoking at times, or at least so it seems, as recovery from an operation. The relief of pain, then, is extremely important for physician and patient.

This category accounts for approximately $100 million in volume. Except for the narcotics, it is difficult sometimes to draw a clearly dividing line between prescription and "over the counter" compounds in this field. Consequently, the foregoing figure includes ethical and nonethical products. The products primarily restricted to prescription use account for 53 percent of the total. Aspirin and related compounds account for approximately 29 percent of the total. Purely proprietary analgesics such as some of the muscular rubs and antiacid analgesic preparations account for the remaining 18 percent.

Tranquilizers.—It hardly seems necessary to mention the word "tranquilizer." Everyone has heard it. Some joke about it. Others misunderstand the true role for these drugs. They are not curative but they are among the best chemical crutches ever developed by researchers. One has only to examine the statistics concerning the freeing of patients formerly committed to mental institutions to appreciate this miracle of modern medicine. And yet, this is one of the newest product groups to attain major importance in the pharmaceutical industry and

is one of the most dramatic examples of product explosion. The group currently accounts for approximately $100 million in sales.

Cardiovascular agents.—Headlines feature stories about diseases of the heart and blood vessels. While most involve those in the older age groups no age group is immune to accidents of the cardiovascular system. Research is feverish in this area but so far the causes of disease are poorly understood. As a result, treatment and curative measures are very important; prevention is still in a pioneering stage.

This group of products accounts for $67 million in sales. Included are hypotensive agents, vasodilators, and cardiac stimulants.

Antispasmodics.—The relief of spasm whether it be for voluntary muscle such as the muscles in the arm or for the involuntary muscle found in the wall of the intestine is very important for many patients, particularly for those who suffer pain from this system. The needs are not yet fully determined but it is an area of great medical interest.

This field, which has had its most dramatic growth and product development in the post-World War II era, now has a total volume in the amount of $48 million.

Antihistaminics.—Anyone who has severe attacks of hay fever does not think it is the source of much amusement. For them relief from drugs is a merciful blessing. The antihistaminics are widely used for allergy in its various manifestations but they also are useful for other medical discorders, a fact sometimes not sufficiently appreciated.

This is another major field which has had its greatest development since World War II. Total volume amounts to $43 million. Since the first major breakthrough in the mid-1940's, a variety of newer compounds with additional features of effectiveness and safety have been introduced by a number of companies. In addition to the basic antihistamines—representing 65 percent of the total—many of these products have been combined with other ingredients to produce special formulations for special purposes. Most widely used of these formulations have been those used for cold remedies. This type of product represents 35 percent of the total antihistaminic volume.

Hematinics.—The correction of anemia is a problem that long has confronted the medical profession. While this is often thought of as a "rundown" condition it can be very serious and the correction of blood deficiencies is medically extremely important.

This product group accounts for $39 million in sales.

Central nervous system stimulants.—Unlike the tranquilizers which are used in part for their calming effect, another group of drugs is used for a stimulating effect on patients. Sometimes patients are simply depressed and are called moody; sometimes the depression is so great they are committed to hospitals. For such patients chemical stimulants are important. Furthermore, there are times when sudden sharp stimulation of the brain, which is part of the central nervous system, is lifesaving; for example, during anesthesia or after shock.

This group accounts for $37 million in volume.

Other product groups.—Other product groups of significance are antidiabetics, $33 million; dermatologicals, $33 million; diuretics, $32 million; ethical cough preparations, $29 million; ethical laxatives, $29 million; vasoconstrictors, $29 million; sedatives and hypnotics, $28 million; biologicals, including polio vaccine, $27 million; sulfonamides, $26 million; antiseptics, $25 million, and others.

By the time this statement appears the figures quoted above may, of course, have changed considerably.

RESEARCH

Research is full of failures. But there are outstanding successes which bring their rewards. Of course, sale of products is important to business in our country, but in the drug business there is an additional reward, that of adding to the welfare of mankind. The conquering of disease, the saving of lives, the adding of years of comfort are sources of deep satisfaction to the drug manufacturers and their employees as they are to the prescribing physician.

At this very moment, enormous amounts of time, money, and hope are being expended on searches which will prove to be dead ends, on compounds which will prove to be valueless, on initially promising experiments which will end in no gain.

Yet where the probable may prove to be impossible, the impossible may suddenly be achieved. This has happened, many times. One compound in a thou-

sand may lead to a shattering breakthrough, and therein lies our absorbing interest. For example, as previously noted, in 1958 there were isolated and subjected to biological tests or screening 114,600 chemical substances. In 1958, about 1,900 chemicals were tested on human tissues under carefully controlled conditions. In 1958, 44 new chemicals were evaluated in the United States; 16 other new chemicals came from non-U.S. sources.

Research may start at almost any point—in a jungle outpost, in a university laboratory, in an industry removed from drugs entirely. The very breadth of this research requires quantities of the most skilled manpower; one company estimates that the amount of time spent at the lab bench alone, by scientists engaged in only one preliminary screening operation, was in the neighborhood of 58,000 man-hours. If the job had been done by one man alone, it would have taken him approximately 19 years to complete it, and even in the case cited the time to perform this one operation successfully was 2 years.

RESEARCH AND DEVELOPMENT

In a typical company research and development (R. & D.) has the responsibility of finding and testing promising compounds in an effort to produce valuable new medications for the treatment of disease. The two functions, though related, are really quite different from each other. Research is an operation which can be compared to a series of sieves designed to sift out the most promising compounds from hundreds of possibilities. In many instances, the kind of sieve needed is not known and research on new methodology is undertaken to derive if possible the kind of sieving mechanism needed. After a lot of highly skilled experimental work, research decides which few of the many possibilities may be probabilities. Animal tests are used to characterize a compound's biological profile, both from the point of view of potentially useful properties and toxicity. Only after results in animals show it to be safe and potentially valuable is the compound evaluated clinically. Research usually supervises the first cautious trial in man—dose range studies, for example. If the compound still looks promising, development takes over.

Development takes those compounds it gets from research—and from other sources—and subjects them to extensive biological investigations, majorly clinical, and also "puts them in a bottle" with instructions for their use. Thus, development determines whether or not the drug seems worth marketing, and decides in what form or forms a worthwhile drug should be marketed.

In 1958 and 1959 the industry spent sums of money for research which even a few years ago would have seemed almost astronomical. A concise tabulation reveals the following:

	1958	1959
(1) Amount spent within companies for research and development	$156,600,000	$174,700,000
(2) Amount spent outside companies for research and development (contracts or grants to universities, hospitals, etc., for specific projects	13,400,000	15,300,000
Total for research and development	170,000,000	190,000,000
(3) Unrestricted grants, contributions, gifts to schools, hospitals, etc., for unspecified purposes, not included above	5,260,000	5,960,000
(4) Contributions or gifts to organizations which in turn support medical and related schools (not included above)	1,900,000	2,000,000
Total industry expenditures for research and development, and for medical and related education	177,160,000	197,960,000

Of the total expenditures cited here, $20,560,000 went in 1958 to medical and related schools, hospitals, and similar organizations, as the pharmaceutical industry's support of these institutions as such, and for support of research being conducted in them.

As already mentioned, for the entire PMA membership, 114,600 chemicals, mixtures, filtrates, etc., were obtained or prepared, and were tested biologically or pharmacologically, as defined above. In the clinical field, 1,900 substances were tested in humans, in 1958.

In addition to the 114,600 chemicals and other substances reported here, a great many more materials of all kinds, including samples of plants and of soil from various parts of the world, were obtained and subjected to routine preliminary screens to ascertain if they possessed any physiological activity.

An important phase of health research, which is sometimes overlooked by those outside the field, is the cost involved in preparing, isolating, or otherwise obtaining large numbers of chemicals, antibiotic filtrates, and other substances for testing, in the hope of finding a therapeutically useful material. Some experts estimate that about one-half of the total research expenditure must go to support the work of organic chemists, biochemists, and other scientists in synthesizing, purifying, modifying, and preparing suitable substances for subsequent physiological tests.

To obtain only one drug for clinical investigations, 60 substances on the average were prepared and biologically tested in 1958. Thus, many materials must be carefully tested in animals before one is found suitable for further investigation in the clinic.

Now, this does not mean that every drug studied in the clinic will eventually reach the market. Instead, it must be remembered that 44 completely new chemicals were marketed by the industry during 1958, according to the yearly report of a reliable marketing consultant. Of these 44 new drugs, 16 came from non-U.S. sources, and 6 represented minor modifications of older drugs. Thus it can be said that the expenditures during previous years of the U.S. pharmaceutical industry in research and development resulted in market introduction in 1958 of from 20 to 30 really new drugs. Each new drug marketed can be regarded as having had back of it some $6 million in total industry research and development expenditures as its share of the combined research effort. Of course, only a few of the 44 really new chemicals or substances marketed during 1958 will become outstanding commercial successes, although it must be recognized that practically all of them represent successes in research or medical science.

The costs of research and development are great. Research administrators estimate that the simplest antibiotic filtrate requires from 60 to 200 skilled man-hours for preparation and testing. To synthesize and test a new chemical, some 400 man-hours are required, as a minimum. These rough figures hold only if the biological tests are disappointing; that is, if negative or medically useless results are obtained. If the new substance looks promising, research time skyrockets, because many more tests must then be run.

Some industry accountants use a figure of $10 per man-hour for ordinary research time costs, but it must be remembered that scientific work cannot be categorized and costs estimated in a simple fashion. To build and maintain an effective research organization requires a substantial investment; each scientist of Ph.D. training or its equivalent, with necessary technical help, laboratory animals, equipment, supplies, and administrative services, costs a pharmaceutical house about $40,000 per year. This figure is estimated at various levels by organizations of differing size and scope; some companies set the cost at $30,000 per responsible scientist, others at $50,000, and others as high as $75,000.

Some idea of the breadth of industry exploration is evident in the following table which hows some of the medical categories in which the industry is doing research.

Medical categories (according to NIH organization)	Number of chemicals, compounds, or other substances, prepared, obtained and biologically tested by industry in 1958	Number tested clinically (in humans) by industry in 1958
Allergy and infectious diseases	50,300	695
Arthritis and metabolic diseases	6,300	405
Cancer	28,000	60
Heart	8,200	187
Mental health, and neurological diseases and blindness	12,100	313
Miscellaneous	9,700	240
Total	114,600	1,900

NOTE.—The Pharmaceutical Manufacturers Association requested its member firms to furnish, on a confidential basis, the number of chemicals, compounds, mixtures, or other substances prepared or obtained for a medical research purpose, and biologically tested so that they could be classified into the medical categories shown above, which represent the fields of interest of the various National Institutes of Health. In addition to the substances reported here, a great many more materials of all kinds, including samples of plants and of soil from various parts of the world, were obtained and screened to ascertain if they possessed any physiological activity. No doubt many individual compounds were tested by more than a single company and many individual compounds were subjected to more than a single biological study.

Some of these figures deserve special comment. It is obvious that the 50,300 materials obtained and tested for "Allergy and Infectious Diseases," include at least some of the results of mass antibiotic screening research programs, while many of the 8,200 substances in the "Heart" field came from elaborate projects of organic synthesis. These 8,200 compounds probably represent at least as complete coverage of the cardiovascular research field as the 50,300 compounds studied in the other research group. Incidentally, companies were requested to omit figures on routine soil sample preparations in preliminary stages; otherwise, the 50,300 total would surely have been much larger.

The 28,000 items reported under "Cancer" no doubt include some, but not all, of the compounds furnished by industry, and screened outside of company laboratories under Government contracts. In this medical category, the relatively small number of clinically suitable products found, when compared with the large quantity tested in the laboratory, demonstrates the tremendous difficulties encountered in the treatment of humans.

On the other hand, scientists are able to prepare relatively more materials of clinical promise in the fields of "Arthritis and Metabolic Diseases," and in cardiovascular research.

Research

Research is carried on by a number of program teams. Some programs are concerned with particular therapeutic areas (e.g., cardiovascular, neurological) while some are concerned with a more general, across-the-board type of screening which looks for activity of any kind to provide a lead. Promising compounds can then be passed on to the therapeutically oriented programs.

Here's where the sieves start to work. The compounds they sift come from many different places: From our own laboratories, from outside consultants, from other industries; or from academic sources. As soon as they arrive they are subjected to some routine, but rather important, preliminary screening tests in animals.

If the compound fails these preliminary tests, it is discarded. If it looks interesting, it is subjected to additional tests. If it fails to pass these tests it is usually cycled back to medicinal chemistry. Why is it recycled? The answer is that a good bit is now known about the compound—its structure, its activity, its toxicity. These data are used by the medicinal chemist to design other compounds something like it—analogues, homologues—which he hopes will not have the defects of the original compound. In other words, this recycling enables us to use what we know to find out what we would like to know.

The cycling process with molecular redesign continues until the lead is played out or until a compound that shows significant physiological properties with mimnimal toxicity is produced.

This toxicity factor is a formidable barrier. Many otherwise promising compounds fail to cross it. They may have an adverse effect on, for example, the blood-forming organs, the central nervous system, or the cardiovascular system.

When a compound has successfully gone through the tough obstacle course set up for it, it is then given a very cautious trial in a few patients by one or two specially trained research physicians. If the compound survives this testing, research has done its job. This research proccess can take almost any amount of time, but generally requires from 1 to 5 years. The compound that completes it is known to be relatively safe and probably useful. It then goes on to development.

Development

The development process usually consists of two parts. The first is exploratory development where the data on the research compound is reviewed. Exploratory can be considered a kind of "waiting room" where compounds stay before being admitted to the inner sanctum. Many compounds never get past this "waiting room." (In addition, exploratory seeks compounds for potential development whose biological activity has already been established by other industrial sources, both here and abroad. It evaluates product possibilities from these sources along with compounds from our own research.)

The research compound moves then into the second stage of the process, full-scale development, carried on often by a development project team established for each product. This team, headed by a senior scientist who is an associate director of development, is made up of a physician, a literature scientist, an administrator, and one or more laboratory scientists. The team will plan and

direct the product's career in development until it is ready for marketing. Several simultaneous operations now go to work.

Clinical evaluation is perhaps the most important of all development operations. The studies already set up by research and exploratory continue, and new ones are added. Their objective is to determine the new drug's specific place in medicine. These studies are conducted by a small group—5 to 10—carefully chosen experts in the appropriate field of medicine. The experts are usually people in medical schools or large clinics. These studies are called primary investigations with the purpose of testing the product's efficacy, and trying to establish proper dosage. They are very carefully controlled and usually compare the new product both with established drugs and with placebos. These studies are very exact. If the primary investigations show good results, secondary investigations are begun. The drug is studied by additional selected investigators, including specialists in private practice. The word "secondary" merely refers to the sequence of study. Although studies done in private practice can't be as highly controlled as those done in hospitals or clinics, they are equally important. The doctor himself is a therapeutic agent. So is the environment. Depending on who gives it and where it is given, the same drug can produce different results in the same type of patient. A new tranquilizer, for example, may have a much different effect when it is given in a State mental institution from the one it produces when given by a psychiatrist in private practice. And the nonpsychiatrist, the internist or general practitioner, may get still different results. It is, therefore, very important to conduct studies evaluating the new drug's efficacy and usefulness in private practice.

Primary and secondary investigations define the drug's medical value. But any study, even a fairly informal one, imposes controls that do not exist in everyday medical practice. Although these studies often suggest, they cannot predict the drug's acceptance by physicians and patients when it is given under the ordinary conditions of everyday practice. Therefore, as the final phase of its clinical testing program, development conducts what is known as a premarket survey. The drug is distributed to a panel of clinicians who report on their opinion of the drug's advantages and disadvantages. These reports not only give some indication of how the drug will fare commercially, but also frequently reveal additional medically useful information.

In other R. & D. areas a lot of things which had been going on before the clinical studies began continue during the studies and often are still going on after the clinical phase is over.

Pharmacy is, and has been, busy developing the most appropriate dosage forms (e.g., tablets, capsules, ampoules) for the drug. At the same time that researchers are supplying clinical investigators, they are conducting stability tests on the preparation. The clinical results themselves sometimes tell us the type of pharmaceutical form that is most suitable.

Pharmacology usually has to make additional animal tests to answer questions that come up during the studies. And they continue their chronic toxicity tests, involving several different species and many observations, for 3 months to 1 year or 2 years to meet the requirements of the Food and Drug Administration (FDA). These toxicity studies alone can cost from $50,000 to $100,000 for each new candidate drug. Organic chemistry is looking into sources for raw materials; figuring out how laboratory synthesis can be adapted to large-scale manufacturing. When pilot commercial batches become necessary, manufacturing steps into the picture. If the drug has passed all these tests with flying colors, the project team will recommend to management that the drug be marketed. The marketing, then recommendation, is considered by a number of committees. If it is approved, a lot of other things start happening.

The legal department agrees on trade and generic names for the product. Manufacturing begins making plans for full-scale production, and FDA submission is made to Washington. This submission is a complete documented survey of pharmacology, clinical data, stability data, manufacturing methods, all assay methods and results, labels, and packages and claims. It often takes up several thick volumes. If FDA raises no objections, or doesn't ask for additional data, finally—at long last—the product is marketed. The average time required from moment of discovery to day of release for marketing is 4 to 5 years.

All of this is only the barest outline of the research process, and does not do justice to the many dedicated men involved in the search. It is a complicated path, involving medicinal chemists, biochemists, organic chemists, microbiologists, virologists, physicists, pharmacologists, pharmacists, physicians, biostatis-

ticians, literature scientists. A recent study by General Electric Laboratories revealed that in the pharmaceutical industry the ratio of scientists to general employees is 3½ times higher than in chemical, petroleum, or electrical industries—all of them major research industries.

The 20,000 steroids and the more than 5,000 sulfa drugs which have been developed, only to be discarded, represent 25,000 separate instances of failure. And 5,000 chemicals, but failures all, were synthesized before a lifesaving antituberculosis drug was developed by three different firms at the same time.

The fruits of pharmaceutical research have revolutionized the practice of medicine. The years ahead will almost undoubtedly see even greater advances resulting from the successful development of important new drugs. But although pharmaceutical research strives constantly for success, it has learned to live with failures. Not unhappily, for from failure comes the knowledge necessary to achieve success. In addition to the occasional success, 1 compound in 1,000 that makes it, medicine owes a great deal to the failures, the 999 that don't make it—and to the industry which gambles heavily that each and every one of them has promise.

Assurance of purity

After a product is developed thorough research, procedures are necessary to assure quality control or continuation of the same pure and safe drug so that the physician can be confident that the results will be as he would expect within the physiologic boundaries of his patients. Thus a modern pharmaceutical manufacturer must maintain control laboratories and trained people to provide this safety factor. This important function of the industry will often equal in size and expense the technical development function. For example, a typical manufacturing process for a tranquilizing drug requires 38 employees, 14 departments, 114 operations, 134 tests and assays, 24.7 days, and 31 raw materials.

THE DISTRIBUTION PROCESS

The products of the ethical pharmaceutical industry reach the utlimate consumers through the groups listed below (figures are for the United States only).

	Number in United States (approximately)
Physicians with an M.D	170, 000
Osteopathic physicians	12, 000
Hospitals (including osteopathic hospitals)	9, 000
Retail pharmacies	53, 000
Pharmacists	110, 000
Drug wholesalers	2, 800
Veterinarians	16, 000
Veterinary hospitals	4, 000

NOTE.—Other groups include military procurement agencies, and medical (first-aid) departments of industrial organizations.

A distinguishing characteristic of the ethical pharmaceutical industry is that, in very large part, its sales and promotional activities are directed at these categories.

The 140 companies comprising the PMA might be divided into 2 groups: Those having national distribution, and those having regional or local distribution. Roughly one-third of the members may be classified as having either regional or local distribution only.

In the pharmaceutical business, the availability of supplies is a medical necessity, and adequate stocks of products must be kept constantly on hand throughout the entire Nation. The four principal components of the distribution chain are the drug wholesaler, the retail pharmacist, the hospital, and the doctor himself. There is little uniformity in the distribution methods used by manufacturers, and variety runs all the way from those who distribute exclusively through the wholesaler to those who sell only directly to doctors.

There are approximately 53,000 retail pharmacies in the United States ranging in size from the small neighborhood pharmacy to the chainstores. They all have one thing in common, however, a prescription counter. In 1958, according to trade sources these stores filled 372,630,000 new prescriptions and refilled 282,480,000 prescriptions. In 1959, the total number of prescriptions filled was 711,660,000.

Most of the larger pharmaceutical companies have warehousing facilities in principal cities throughout the country. Sometimes they are combined regional sales offices and warehouses; but the branch system, as it might be called, is a definite part of the distribution process.

Dated merchandise and the returned goods problem

An extremely important problem in our distribution process relates to dated products; that is, products where the Government specifies that such products are to be used prior to a certain date, to insure proper potency and safety. To cite an example with which we are all familiar, polio vaccine has a "dating" of only 6 months.

Biological products and antibiotics are the principal categories affected by datings. To give a specific example; one large pharmaceutical manufacturer lists 40 biological products, each of which has a dating—some of 6 months, others of 18 months, several of 2 years, and a few of 3 years. That same manufacturer lists 42 antiobiotic preparations, each one bearing an expiration date. It is estimated that a considerable part of the 1958 sales volume of that manufacturer was represented by preparations bearing a dating of 18 months or less.

Solutions for hypodermic administration, whether in multiple-dose vials or in ampoule form, are preparations having a normal life of about 2 years. Generally speaking, other pharmaceutical products have a normal shelf life in the retail pharmacy or hospital of not more than 4 years.

The dating problem inherent in the industry brings along with it the problem of returned goods. Generally speaking, pharmaceutical manufacturers all have what might be termed a "liberal returned goods policy." In some instances the returns in biological products have amounted to as much as 40 percent in a given year.

Scientific inventory control

Most, if not all, pharmaceutical companies have to contend with fluctuating seasonal demands. Many new approaches to inventory control have been adopted by the pharmaceutical industry since World War II. Scientific consideration of production operations has brought about such new methods as controlled inventory limits, mathematical formulas for determining lot quantities and lot sizes, sales forecasts related to production forecasts, shortening the length of time to complete a production operation to reduce the amount of inventory needed, and accurate determination of machine capacity. Such efforts have done much to reduce unnecessary waste and expense.

The professional service representative

A key factor in getting medicines off the shelf and into use is the professional service representative, often referred to as a detail man, since he can supply the physicians with details about products. As I have said, he is considered by many to be the most effective means of providing technical information, especially on new products and extended or new uses for old products. He not only informs the doctor what the new products can do but what side effects or toxicity the doctor must watch for. In a survey by the American Medical Association, approximately two-thirds of the physicians in America rated the detail man as their top source of new product information.

The larger pharmaceutical companies may employ as many as 1,000 professional service representatives. The middle-sized and smaller companies naturally employ a smaller number and are more inclined to depend on other means for disseminating information about their products.

Pharmaceutical companies select these men with care. Many are pharmacists, most of them have college degrees, usually in the sciences, and all of them are trained carefully. The competent representative can save the phyician much time in keeping him supplied with the technical information concerning new products.

The detailer's job

When the representative calls on the physician he brings with him reprints of scientific papers that have appeared in medical journals, visual aids designed by his company's promotion department to provide information quickly and accurately, as well as samples of the product. Furthermore, he is an immediate source of answers to questions the physicians may have, or is a means of channeling more complicated questions to his company's medical personnel. But this

is normally the most expensive means of providing technical information. The number of calls made by a representative usually averages only six to eight per day.

This professional service helps reduce the timelag between scientific discovery and its application at the bedside. Patients everywhere benefit; frequently lives are saved. It is conservatively estimated that in the United States 15,000 men are employed in this capacity by pharmaceutical companies at the present time.

OTHER MEDICAL EDUCATION SERVICES

The wide-ranging educational activities of the industry—a source of considerable pride to our member companies—have had far-reaching consequences in medical education and professional communications. This contribution, primarily, has been to provide new vehicles by which the geometric progression of medical knowledge can be made usefully available to the practicing physician. The activities include medical publications, symposia, television, exhibits, motion pictures, and recordings—in addition to substantial support in the form of fellowship grants, scholarships, and contribution for the maintenance of medical faculty, and grants for basic and applied medical research.

Costs to individual companies for these purposes run into hundreds of thousands of dollars per year. One company has spent some $300,000 in 4 years to underwrite educational programs at medical society meetings. Another company has expended $2,500,000 over a 10-year period for medical use of closed-circuit color television. Still another company has spent $1,500,000 over a 6-year period to help support medical college faculty members. These represent only part of the funds poured into the complex structure of medical education in this country by the pharmaceutical industry. Research grants by the industry to teaching hospitals, universities, and research institutes in 1958 alone approximated $20 million.

Educational television, radio, tape

Through pharmaceutical industry initiative and support, dramatic new teaching techniques have been placed at the disposal of the Nation's physicians, and as an important byproduct of this effort, electronic methodology itself has been revolutionized. A member of our industry made the first practical use of color television as an important breakthrough in postgraduate medical teaching. Several companies made pioneering contributions in the use of nationwide closed-circuit television broadcasting, again for postgraduate purposes. A recent experiment linked five medical schools together by means of closed-circuit television for a series of teaching sessions on forensic medicine. Another company has contributed technical television advances in the area of large screen high-intensity equipment. Soon after the installation of a new transatlantic telephone cable in 1956 a member of our industry initiated medical seminars between the United States and England, to bring internationally prominent experts together for an exchange of the latest approaches to major disease problems.

Important experiments in the use of FM radio for medical and hospital conferences, and for transmitting timely medical news to practitioners, are now underway. And several companies have employed tape recordings as a convenient method for the physician to receive pertinent reports of conferences and abstracts of professional papers.

Medical publications

It is important to note that the programs here under discussion are not concerned with the promotion of specific products. By and large, however, the literature and other efforts which are concerned with specific products also conform to helpfully informative levels of medical communications and serve important purposes in bringing new technical information to the physician as quickly as possible.

Good examples of nonproduct literature prepared by a pharmaceutical house to aid the physician in treating his patients are booklets which are pictorial guides on such subjects as arthritis, rheumatism, anatomy of eye, ear, nose, throat, and others. These are planned to assist the physician in the difficult task of explaining disorders to his patients. In addition, other companies prepare expensive color atlases of normal anatomy, of skin diseases, of nervous systems and disorders, and a great many others.

Physicians' reference books on diagnosis and treatment of allergies and other diseases, a booklet on techniques and equipment of parenteral administration, and countless other publications which are constantly reissued to keep up with fast-moving advances flow in a continuous stream from the pharmaceutical houses to physicians' offices, to hospitals, to medical schools, and to pharmacists.

Impressive and useful periodicals are issued to keep the physician informed. A partial listing of the contents of one of them is available.

In such publications the editing and writing is done by experts in the various fields.

Films

The great majority of motion pictures used in the teaching of various phases of medicine and surgery have been prepared or paid by the pharmaceutical industry. There is scarcely a company of any size that does not maintain an outstanding library of medical films that are made available to medical groups free of charge

One company maintains a library of some 3,500 prints of surgical films covering more than 300 subjects, which represents an investment in excess of $3 million. These are seen annually by an estimated 300,000 doctors, nurses, and medical technicians. Another company maitnains an impressive library of films on the treatment of mental disorders. These showings over the years have reached audiences numbering in the millions. Other subjects by other companies cover such titles as: "Living Blood"; "Diagnosis and Treatment of Myasthenia Gravis"; "Continuous Spinal Analgesia in Ceasarean Section"; "Studies in Human Fertility."

Medical symposia

The medical symposia programs are of great importance in furthering the postgraduate education of the practicing physician. Sponsored by various companies, these bring outstanding medical authorities to various medical groups across the country. In many cases postgraduate study credits are giving to physicians who attend these company-sponsored lectures. One company has sponsored some 150 of such symposia with total physician attendance running to about 35,000.

Industry support of education

The amount of money spent by members of the pharmaceutical industry in the United States is not known. A study of this is now underway. However, some indication of the many millions of dollars involved lies in a few examples readily available.

Since 1953 the drug industry has contributed to the National Fund for Medical Education more than $1,600,000. Several times this has gone directly from the industry into medical colleges and to the students through scholarships, fellowships, and research grants.

Since 1942 the drug industry has contributed to the American Foundation for for Pharmaceutical Education more than $3 million. Several times this amount has gone directly from the industry into pharmacy colleges and to students in attendance through scholarships and fellowships. The importance of such help is evident in the fact that this foundation for pharmaceutical education has awarded more than 500 graduate fellowships since 1946. Of those receiving a fellowship, 187 are teachers in 69 U.S colleges of pharmacy, 131 are in research and development fields, 16 are in Government service or professional association, 26 are continuing graduate or professional studies and 6 are holding postdoctoral fellowships. Close to 2,000 undergraduate scholarships have been awarded at a total of 71 colleges of pharmacy.

Since 1948 the U.S. drug industry has contributed at least three-quarters of a million dollars to the U.S. Supporting Committee of the World Medical Association, an organization interested in medical problems throughout the world and which took pioneering studies twice within 6 years when it held world conferences on medical education.

As an example of a more limited, geographically, affiliation consider the fact that the pharmaceutical manufacturers have paid over $9 million in royalties to the Rutgers Research and Educational Foundation, which has been used to further education and research.

Another example of industry support of those interested in medical activities is the program of one firm (which is not unlike in spirit that of other firms), which provides fellowships for training young pharmacologists in a nation other

than that in which he received his previous training. This firm underwrites 4 such fellowships in the United States of America and through a subsidiary firm in England.

Industry support of medical care research

As a group of good business citizens, the pharmaceutical industry has supported a number of public service activities, among them the Health Information Foundation, which was organized 10 years ago to provide information for the public and those responsible for the continual improvement of health services.

During these 10 years, the foundation has been supported by contributions of $5,152,895 from over 200 firms in the drug, pharmaceutical, chemical and allied industries at all levels—manufacturing, retail, and wholesale. The major portion of these funds has been devoted to social and economic research in health, resulting to date in 44 grants to 21 different universities and 7 other nonprofit research agencies; 8 more projects have been conducted by a research staff at the foundation.

The Health Information Foundation is well known as an impartial, unbiased source of primary information essential in planning for improved medical care in this country. As an example, a vital foundation study currently being conducted by the National Opinion Research Center of the University of Chicago is gathering the first comprehensive information on the use of health services by those 65 and over, including data on their coverage under voluntary health insurance and the attitudes of these older people toward their health problems. The population sample interviewed was a scientifically selected group of aging persons. This study is also securing corroborative data from the nearest relative of the older people in the sample and is exploring the attitudes of a cross section of the total public toward the problems of aging.

Other studies by the foundation have provided benchmark information on what people spend for medical care, including physicians' services, hospital care, drugs, dental care, and appliances. I can submit for the committee's examination several reports from such studies to demonstrate the type of research being carried on. For example:

"Private Expenditures for Drugs and Other Components of Medical Care" by Odin W. Anderson, Ph.D., research director, Health Information Foundation.

"Comprehensive Medical Insurance," Research Series No. 9, by Odin W. Anderson, Ph.D., and Paul B. Sheatsley.

"Financial Resources of the Aging," Research Series No. 10, by Ethel Shanas, Ph.D.

"Measuring Health Levels in the United States, 1900–1958," Research Series No. 11, by Odin W. Anderson, Ph.D., and Monroe Lerner.

The industry takes great satisfaction in having supported this useful research, mindful that precise information, while serving to document progress, also illuminates problems in need of solution in every component of the medical care field. These studies sponsored by the foundation have, in fact, been useful to health planners in every aspect of medicine. They clearly show that in improving the health services of this country, there are intimate interrelationships between all the components of service—physicians, hospitals, dentists, the drug industry, and voluntary health insurance—and that only by considering the total constellation can effective improvement in the distribution of care be attained. The pharmaceutical industry believes that through its 10-year support of the foundation it has assisted fundamentally in improving medical care countrywide.

There follows a brief description of a few of the surveys:

1. *Massachusetts hospital study.*—This is a survey of a representative sample of hospital discharges in Massachusetts for a year to determine how hospitals are used in a modern society with modern medical care. The study was precipitated by the concern with so-called "abuse" and "overuse" of hospital care stimulated by easier means of paying for care, such as insurance. The Foundation felt that information was necessary to raise the level of discussion on this problem. With the National Opinion Research Center we will learn from the patient after discharge, from his family and from the attending and referring physicians the context in which decisions were made to hospitalize and to discharge. The physicians' specific medical reasons, i.e., appendicitis, pneumonia, etc., are taken as given, but the social circumstances of the patient will be explored, the type of practice of the doctor, presence or absence of certain facilities, and source of

payment to the hospital. With such data we hope to show the patterns of hospitalization in sufficient detail and in such form that those who wish can apply their own criteria.

2. *History of the development of health services in Great Britain since 1900 culminating in the National Health Service of 1946 (estimated cost, $20,000).*—The purpose of this historical study is to determine how a country like Great Britain, basically similar to the United States in political and social institutions and professional values, turned to nationalized health service like the National Health Service. It is expected that the stages of development during which debates raged and decisions were made to go one way or another and the range of alternatives present will be recreated, and the ultimate results of such decisions. This may give us some insight into developments in the United States and determine what viable alternatives exist here. It can certainly be said now that no country has ever had the opportunity to make voluntary health insurance the backbone of financing health care as has the United States.

3. *Intensive study of two medical bureaus in the State of Washington, King County and Okanogan County (estimated cost, $73,000).*—This is a study of subscribers, participating physicians, and internal administration of two county medical society sponsored and operated physicians' care plans offering the full range of physicians' service on a prepaid basis and paying physicians fees-for-each-service in their private offices. The Foundation felt that it would be of value to show Blue Shield plans that it is possible and practical to offer home and office calls in the prevailing structure of medical practice. A similar study already published was Windsor Medical Services.

4. *Public attitudes toward health services (estimated cost, $180,000).*—Following our nationwide family cost survey of 1953 it was apparent that the variations in use of services in the population could not be explained by economics alone, the time-honored sole variable. We then embarked on an intensive attitude study of a representative sample of adults in the U.S. population with all the usual variables of age, sex, residence, income level, educational level, etc., to learn how they perceived the doctor, the hospital, their concept of health and sickness, and the barriers to use of services, the economic reasons among them.

5. *Survey of the aged (estimated cost, $150,000).*—This is a survey of a representative sample of people 60 years of age and over in their own homes to determine how they view their life problems with particular reference to health services. The Foundation felt that a very one-sided view of the aged has prevailed because the problem was defined primarily by physicians, social workers, and others who are exposed daily to the hard core of the problem. A survey of a representative sample would give us a better idea than before of the components of this problem and isolate the hard core from the rest. A sample of those next in line of responsibility mentioned by the aged, i.e., son, daughter, other relative, friend, to get some idea of mutual responsibility in American families today.

6. *A resurvey of a national sample of families like the one done in 1953 to determine the distribution of the costs of health services among them, the extent of health insurance, and what the insurance was doing to help families pay for care (estimated cost, $60,000).*—An added feature to this survey compared with the one done in 1953 was that a much larger sample of families with relatively high costs in a year, i.e., $500 or more, was drawn so that there could be a more refined analysis of these "catastrophic" groups than was possible previously.

7. *Survey of how families spent their incomes and the priorities they placed on goods and services purchased (estimated cost, $22,000).*—Approximately 500 complete families with father, mother, and at least one child were interviewed intensively as to the priorities they placed on goods and services claiming their incomes. Particular reference was paid to health insurance and health care. This was a kind of "market" survey for the health field.

8. *Survey of members of three labor unions in New York City enrolled in Group Health Insurance or Health Insurance Plan of Greater New York (estimated cost, $52,000).*—This was a household survey of members and dependents in three trade unions who selected GHI or HIP, two contrasting types of methods of providing physicians' services, reasons for choice, attitude toward doctors in the two plans, costs, and utilization of services. The Foundation felt this was a timely study because of the emerging competition between free-choice fee-for-service plans and closed panel type plans.

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Education for the public

In addition to the educational efforts aimed at the medical profession the industry provides the general public with information on good health care. One outstanding program of public service advertising in national magazines has been running for more than 30 years. Another company issues a pocket reference book for diabetics which has become a model publication of its type and is issued upon request. Information pamphlets dealing with medical research, as well as health care, are directed to the layman by the pharmaceutical houses.

Nationwide public telecasts on medicine—one series of which has been on the air for the past 8 years—have been initiated by members of the pharmaceutical industry to serve both the profession and the public. The programs have assisted the medical profession in creating greater public understanding of medical research and practice. They have reported on the major medical meetings, the outstanding research centers and hospitals, the medical schools, the work of American doctors throughout the Nation and the world.

The industry has been in the forefront of pioneering in the use of the newer media to bring more and later information to physicians all over the world. These efforts have undoubtedly helped in saving more lives, but perhaps of equal importance they have demonstrated that such life saving can be the product of a political-economic system based on vigorously maintained freedoms and responsibilities.

INTERNATIONAL ACTIVITIES

Medical science from its beginnings has been international in scope. Disease knows no national or political boundaries, and the search for an application of medical discoveries is worldwide. International research and international cooperation involves thousands of scientists, doctors, nurses, students and writers throughout the world. Manufacturing, packaging, and marketing of drugs by U.S. firms in foreign lands has expanded rapidly, particularly during the past decade.

An example lies in a survey by the Federal Trade Commission (1958) which revealed that 10 leading U.S. firms in 1950 operated 4 manufacturing plants and 25 packaging facilities in 22 foreign countries. By 1956 the same companies had 19 manufacturing plants and 77 packing plants in the same countries. Even relatively small U.S. companies now sell their drug products in as many as 20 foreign countries; the larger companies list sales operations in as many as a hundred countries throughout the world.

Research and medical education similarly have been extended; it is estimated that as of today, upward of 650,000 physicians in all parts of the world receive information from U.S. companies. Both the United States of America and its neighbors of the world community benefit from the vast exchange of medical knowledge. Americans spread scientific knowledge and in turn foreign scientists brought to the Western Hemisphere by pharmaceutical firms bring the benefit of their own skills and fresh viewpoints. In fact, U.S. companies often are approached by foreign governments who wish to utilize the knowledge and experience of our industry. International conferences of scientists and doctors bring together the best each country has to offer; in some cases the U.S. companies assist scientists to attend such conferences who otherwise would be unable to meet the travel costs.

International operations of U.S. drug manufacturers may be divided roughly into three classifications for descriptive purposes: Research, manufacturing, and education. In each of these great areas the Americans drive toward the goal of better health, wider medical knowledge, and worldwide advance in the battle against illness and disease.

Research

There is no geographical "center of research"—the pharmaceutical industry's contribution of some $190 million annually is a large factor in U.S. operations but also spreads to scores of other countries. Research into diseases peculiar to tropical climates, for example, often is conducted by U.S. firms, using foreign scientific personnel, in the countries where the diseases are most prevalent. And some of these findings of clinical trials, conducted entirely in a foreign land, may, at times, be part of the presentation to our own Food and Drug Administration as evidence of the efficacy of a new drug. In some cases the Americans themselves do not conduct the search, but make research grants to foreign institutions. In other cases the research being done in U.S. plants may be aided by foreign scientists.

American pharmaceutical houses exchange scientists with foreign institutions; while technical personnel from abroad are learning about our methods and advances, our own scientists are spending a tour of duty abroad. Thus the two-way exchange of knowledge is constantly widened to reach into the far corners of the world, and the far reaches of man's genius and inventiveness.

Research grants by U.S. firms are a prominent part of the support for foreign explorations into new medicines and treatment of disease. The Americans, fully conscious of the great discoveries abroad which stimulated the march of medicine, look forward to future important findings of the same nature. One U.S. company, for example, during 1958 reported foreign research grants thus: To Canada, 2 grants totaling $8,000; to Mexico, 6 for $24,000; to Haiti, 2 for $20,300; to Chile, 2 for $2,790; to Peru, 2 for $1,700; to Costa Rica, 1 for $1,000; to Great Britain, 10 for $53,000; to Italy, 2 for $3,200; to Malta, 1 for $1,600; to Germany, 1 for $8,000; to Sweden, 1 for $3,000; to Austria, 1 for $4,500; to Portugal, 1 for $875; to Lebanon, 1 for $13,800; to Japan, 2 for $4,000; to Australia, 1 for $1,125; to Liberia, 1 for $2,000.

Thus in 1 year, one typical U.S. firm made grants to scientists doctors, and institutions in 17 foreign countries, of about $153,000. Another company in a single grant awarded $10,000 to the South Africa Research Council for a study of plant life. Still another estimates that its research grants include more than 100 fellowships throughout the world, permitting foreign doctors to spend a year of postgraduate study in the United States. Fellowships awarded by yet another U.S. firm have helped young doctors from 38 different countries with travel and living expense for a year in the United States.

This is but a brief accounting of a few of the research activities which link the United States of America to the rest of the world; through ever-widening application of these policies the U.S. pharmaceutical houses are putting into practice the "good neighbor" philosophy and are helping others to help themselves as together they build a strong world health team.

Education

Educational activities of U.S. companies abroad include not only encouragements to foreign schools and scholars, but a vast effort to keep the world informed about medical advances, wherever they may occur. Not only in offering grants to encourage postgraduate research, but in helping students in their own countries the U.S. firms perform a constant service. More trained technical people, more doctors, more health services are needed throughout the world, in many countries most desperately, and aid from private American companies is channeled into worthy hands constantly, usually upon approval of foreign school authorities, medical deans, or others in charge of furthering education.

Oversea education also is aided by the many scientific international conferences, previously described, in which the U.S. companies make their knowledge available through their own highly trained personnel. To list the conferences held throughout the world on medical and related subjects, for just 1 year, would require several close-printed pages. The American pharmaceutical houses are in the forefront of assisting with the planning, programing, and conduct of scores of such international meetings, and their people go to all parts of the world to take part in such conferences, to make their own knowledge available and to learn from others.

To keep the physician informed, the U.S. companies work along two broad lines: (1) The normal and necessary information needed to evaluate the company's own products; and (2) the spreading of medical knowledge through many media without regard to private business or sale of one's own brands of medicine. All successful companies which operate on an international level work hard at making themselves known, their products known and respected, and to promote sales. What is not so generally known is that they also work hard at promoting worldwide intelligence about health and medicine along lines entirely unrelated to specific drugs. Examples include one well-known company which distributed 190,000 copies of a booklet throughout the world, the contents of which were simply abstracts of important papers delivered at medical conferences in many lands. There was no product reference. Another American company spent some $2,500,000 during the past 10 years promoting color television teaching of surgical and clinical methods; it has presented 878 surgical-operation showings and 1,448 clinical demonstrations in this way to 136 medical meetings. Yet another company has furnished medical textbooks,

charts, films, and anatomical transparencies to some 348,000 doctors, printing the textual matter in 18 different languages.

American manufacturers maintain medical libraries and medical men on their staffs, and these men travel to foreign meetings to make lectures, and help inquiring technicians, teachers, and physicians from abroad. One company has set up a complete medical library in Brazil, for use by local professional people. Several maintain similar compendia in England and the countries of Europe. All work closely with schools, in whatever land the company is active.

Whereas a century ago the common practice was for American doctors to take their postgraduate work (and often their undergraduate work also) abroad, today the United States of America is host to hundreds of foreign medical students, teachers, dotcors, and technical people each year. The American pharmaceutical companies conduct tours for such visitors, hold seminars, help them in many ways. Often such help is extended by the company in cooperation with the U.S. Government, which arranges many tours. As a measurement of this interest, it may be noted that during 1958, one American firm alone reported that it was host to such touring delegations from 42 countries.

Authorities both private and public agree that the spread of cooperative educational activities is a good augury for the future. The U.S. drug manufacturers believe that money and effort are well expended to advance such practical policies throughout the free world.

Manufacturing

The explosive growth of the pharmaceutical industry during the past few years, described in its domestic and overall measurements in earlier sections of this report, has included rapid development abroad. Drug sales abroad account for 20 to 40 percent of the total for many U.S. firms, and the acceptance and usage of the American products increases each year. One example cited in a recent survey shows a leading drug manufacturer's foreign sales in 1950 reached $12 million; by 1958 the same company's foreign sales were $85 million, a result of active expansion into some 50 foreign fields. Another U.S. firm reported sales in 90 countries. Still another sold its products in 120 countries. Not only are large firms thus moving into international competition, but smaller houses also vigorously pursue the same goals. Contributing not only to the better health of the citizens in foreign lands, but to the economies of such countries, the U.S. firms employ foreign personnel whenever possible. Goodwill and public approval are noticeable in the acceptance of the high quality, high standard American products and methods.

Nearly all of the nations of the free world, including many in Asia and South America, are now sites for U.S. drug manufacture, packaging, and distribution. Other American plants are in the planning or building stage. Not all U.S. manufacturers pursue the same method in establishing foreign operations, and some of the larger ones use several of the following major policies:

1. A U.S. firm may build or operate a foreign plant; a subsidiary may build or operate it;

2. A foreign firm may be licensed to manufacture the U.S. company's products, using processes developed by the Americans;

3. A joint arrangement may be made, whereby the U.S. firm and the foreign company cooperate to build and to run the operation, with each sharing in the ownership and direction.

4. One U.S. house may arrange for its products to be made and sold abroad by the foreign arm of another American firm.

Whatever the method, the U.S. firms are alike in one respect—they believe that the problem of maintaining good health is a worldwide problem, that modern science is welcome throughout the world, and that the future will see even greater spread of the desire for up-to-date medical and scientific effort to combat disease and illness. They find, too, that the free world outside of the U.S.A. welcomes our concept of how to reach these goals.

American pharmaceutical manufacturers believe that the days of great discoveries and great achievement in medical history are not confined to the past nor the present, that the future is one of even greater promise.

The findings of the Senate Subcommittee on Reorganization and International Organizations, in its report of April 10, 1959, are greatly to the point. In the foreword to this report the subcommittee states:

"Medical research itself has always had an international character. Medicine has been the beneficiary of discoveries which have transcended national

boundaries. Today the complexity and volume of medical research render especially important the promptest possible exchange of scientific information and strengthened cooperation.

"There is no politics or ideology in a cancer cell. A child in any nation, suffering from, for example, leukemia, evokes anguish in the hearts of parents and other loved ones, and sympathy everywhere.

"Men are linked by common pain and suffering. Men are linked also by the common joy of conquering disease and disability."

GOVERNMENT AND INDUSTRY

The relations between the pharmaceutical industry and government in the United States have been aptly described as "a living example of the free enterprise system working reciprocally with free government." The pharmaceutical industry is subject to an unusually high degree of Government regulation. Its relationship to the Government has not, however, been limited to that required by statute or regulations. Joint action has taken place promptly and voluntarily wherever it has appeared to be in the public interest. The relationships have been characterized by a high sense of public responsibility on both sides and, whether voluntary or involuntary, have been carried forward in an atmosphere of mutual respect.

Government supervision or control affects the industry in its manufacturing, packaging and labeling, introduction of new products, product standards and its advertising and promotional claims.

Summary of regulatory laws

Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301) and rulings and regulations thereunder: An act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, and cosmetics, providing for factory inspection and almost absolute control over the manufacture, distribution, and labeling of new drugs, and batch certificate of drugs containing insulin and most antibiotics. Administered by the Federal Food and Drug Administration (Department of Health, Education, and Welfare).

The State legislatures, through their inherent police powers and also through specific constitutional power such as protection of public health, and the like, have undoubted power to protect their people against adulterated and misbranded food, drugs, and cosmetics.

The enactment of the Federal act in no way affects the validity of the State laws unless the latter are conflicting. The passage of the Federal act was the signal for the initiation of a movement for the passage of uniform State food, drug, and cosmetic acts.

All of the States now have that or similar laws. A number, in addition, require the registration and licensing of branch offices, etc., of manufacturers so as to control the distribution system.

At least 34 of the States have laws controlling the manufacture, sale, and labeling of barbiturates, amphetamines, and other specific drugs.

Virus, Serum, and Toxin Act of 1944, as amended (42 U.S.C., ch. 4) and rulings and regulations thereunder: An act to provide for the licensing by the U.S. Public Health Service (Department of Health, Education, and Welfare) of every manufacturer and every biological product intended for man, factory inspection, and which results in almost absolute control over the manufacture, distribution, and labeling of such drugs so as to insure the "continued safety, purity, and potency" of such products. A number of States have laws regulating these products.

Virus, Serum, Toxin, and Analogous Products Act of 1913, as amended (21 U.S.C., ch. 5) and rules and regulations thereunder: Provides for virtually the same regulation of biological products intended for animals as those intended for man. Administered by the Secretary of Agriculture. It will be noted that preparations may be both drugs subject to the Federal Food, Drug, and Cosmetic Act, and, at the same time, preparations subject to either of the Virus, Serum, and Toxin Acts. A number of States have laws regulating these products.

Federal Trade Commission Act—Wheeler-Lea Amendment of 1938 (15 U.S.C. sec. 41): Provides, among other things, for penalties for false advertisement, other than labeling of drugs. The distinction between this and the Federal Food, Drug, and Cosmetic Act is that this act is concerned with false advertising, while the latter deals with adulteration, packaging, and labeling of food, drugs, and cosmetics. Similar laws have been passed in a number of the States.

Federal Caustic Poison Act (15 U.S.C., ch. 11) and rules and regulations thereunder: Provides for the labeling and shipment of certain caustic poisons therein defined. Administered by the Secretary of Agriculture. The so-called Hazardous Substances Act, introduced into the 86th Congress and expected to pass in the 2d session, will supercede this act and probably place further and more burdensome labeling requirement on virtually all drugs.

Practically all States have poisons and hazardous substances laws which govern labeling and distribution of such products.

Postal service—Nonmailable injurious articles (18 U.S.C., sec. 1716): Provides for the establishment of regulations by the Postmaster General of regulations for mailing or nonmailing of articles injurious to life, health, or property.

Federal Narcotic Act (ch. 39, subch. A, pt. I of the Internal Revenue Code of 1954); Federal Narcotic Drugs Import and Export Act (21 U.S.C., ch. 6); Marihuana tax law (Internal Revenue Code of 1954, ch. 39, pt. II, subpart A): These laws may be largely superseded by the Narcotics Manufacturing Act of 1960 which passed the House in the 1st session and is expected to pass the Senate in the 2d session of the 86th Congress. Implementing our treaty obligations, this law will strictly regulate the manufacture and distribution of all natural and synthetic narcotics and, in addition, will establish quotas therefor.

Practically all States have strict laws regulating the manufacture and sale of narcotics.

The laws in operation

As a layman, it has always seemed to me that the legal regulation of the products of the pharmaceutical industry is quite unusual, in that an individual can be made subject to criminal penalties even though he has had no intention of breaking the law. No doubt a lawyer can describe this concept better than I, but it seems to me really unusual that a person can be a criminal without having any criminal intent. Specifically, there are many criminal penalties in the Federal Food, Drug, and Cosmetic Act resulting from interstate shipment of adulterated drug products, which can be applied to the executives of the company making the shipment, even though these executives were not really aware that the material was not satisfactory.

Perhaps the widest field of contact between the industry and Government has resulted from passage of the Federal Food, Drug, and Cosmetic Act of 1938. Legitimate businessmen seem to have recognized the value to them of the Food and Drug Administration from the beginning. These laws freed the majority of conscientious manufacturers from the unfair competition of the unscrupulous one who manufactures under unsanitary conditions, cheapens his product with low quality ingredients, and falsely labels his product as being better than it is, and at the same time offered added protection to the public from the unscrupulous. "For 34 years," George P. Larrick, Commissioner of Food and Drugs, has declared, "the drug industry and FDA have been cooperating in developing standards for drugs and methods for testing and assaying them." As examples he has pointed to the work of the Pharmaceutical Contact Committee of the Pharmaceutical Manufacturers Association, and collaborative studies made for control of new products and development of better testing methods for compounds included in such official compendia for the "United States Pharmacopeia" and "National Formulary."

Thus, the pharmaceutical industry shares with FDA its advances in assays, standard compositions, and analytical methods for detection of variations from the standard. Industry has worked with the administration in establishing standards and tests for consumer protection with both sides consulting in advance on regulations and interpretations.

The Federal Food, Drug, and Cosmetic Act results in regulatory controls over the strength, quality, and purity of all drug products, and controls over what is said about these products. To meet these requirements, reputable manufacturers maintain most elaborate and expensive control systems. Every raw material is tested as it enters the plant, regardless of the previous manufacturer, of his guarantees, or of tests which he has just finished. All water used must be regularly tested. Each ingredient is carefully measured out or weighed before being introduced into a batch of a drug being manufactured, and it is customary for many companies to require check weighings or duplicate weighings of unusually potent ingredients. Poisons and narcotics require special handling and special attention.

Working formulas are carefully checked to make sure all figures are correct. Each portion of each raw material is carefully labeled so that it cannot be mistaken for another substance, or placed into the wrong batch.

Some companies even use the elaborate precaution of not manufacturing dosage forms which look alike, at the same time, in adjacent or nearby working areas.

During mixing, blending, volume adjustments, heat treatments, filtrations, and other manufacturing processes, quality control samples are taken at appropriate times, and constant surveillance is kept of the material in process. In many companies these operations are watched by inspectors responsible only to the quality control department, and not to the production department.

As each batch is finished, it is meticulously tested, examined, and compared with quality standards. Tablets are measured, weighed, analyzed for active ingredients, and examined for proper appearance. Liquids are carefully measured, filtered, analyzed for active ingredients, and checked for color, flavor, clarity, and general appearance

Products which are supposed to be sterile require special handling and testing, of course.

All of these precautions are made necessary to safeguard the patient, as well as to meet the regulatory requirements I have mentioned. The Federal, State, and municipal laws and regulations require that the label of the product carry the name and quantity of each active ingredient, and of course the laws require that the contents contain the substances and quantities stated on the label. Any special characteristic, such as sterility or an antiseptic property mentioned on the label, must be met by the product contained therein.

The laws and regulations also make sure that label statements and statements of accompanying literature are not false or misleading in any respect. In addition, the Federal law, in the new drug section, contains requirements which have the practical affect of giving FDA review authority over practically all medical claims, and permitting inspectors to go through pertinent files in company facilities at any time concerning these products.

The Federal law, and many State laws, permit authorized representatives of regulatory agencies to enter company plants during working hours, at unannounced times. These inspectors can watch manufacturing operations, remove samples for testing, observe quality control procedures, review working formulas, and scrutinize sanitary conditions. The laws permit them to take legal action against a company not meeting manufacturing requirements.

With respect to labels, most companies are extremely careful about the way tney are handled. First, everything said on the label is reviewed over and over again, by medical authorities, quality control specialists, and others. Quantities of ingredients stated are checked against quantities used in working formulas, to make sure they are correct. Labels are kept under lock and key to protect their integrity. Some companies have automatic methods of checking the label on each bottle or other container, to make sure that one or more labels of the same size, but for different products, have not slipped into the stack.

Each label bears a special number, which is keyed to factory production records. In a reputable company, each raw material used in each batch of every product can be identified from the little number appearing on the label. This means that the number is changed for each batch, or sometimes for each date on which the product is filled from stock.

Many conscientious companies have regular inspection periods for products being held for shipment, either in company shipping rooms or in warehouses over the United States. This insures that batches which might become defective upon standing are not later distributed.

The maintenance of an accurate control number and identification system is important from the governmental standpoint, because this means that the Government can ask the manufacturer to check into the history of any drug sample picked up anywhere at any time. Actual samples of each batch are kept in company files for many years, so that the container examined by the Government, or by anyone else, which may have been found in a drugstore or warehouse, can be checked against an authentic sample of the original batch.

Beyond the area of scientific activity, industry has supported larger appropriations for administration, so that FDA might meet its responsibilities adequately. Industry has lent its support to keep FDA under civil service, feeling that objective enforcement of the regulating law is more likely to come from a career type agency than from a political one.

So far, I have discussed the general requirements of the Federal law, which are duplicated in many State and municipal laws. These requirements apply to all drugs, whether they are biologicals or ordinary pharmaceuticals. There is an additional important law regulating biological products, such as viruses, serums, and toxins.

Biological products are controlled under licenses issued by the National Institutes of Health of the U.S. Public Health Service. Biological control provisions date back to the Public Health Service Act of 1902 (superseded by the Virus, Serum, and Toxin Act of 1944), promulgated "to preserve the confidence of the medical profession and of the community generally" in vaccines, serums, etc.

The law regulating biological products requires that each manufacturer be licensed, and that the product itself also be approved by the U.S. Public Health Service. In evaluating each product, the Public Health Service considers manufacturing conditions, processes, label statements, and medical claims. All establishments, products, and claims must meet Public Health Service approval before the product can be legally distributed.

All of the comments above apply to products for veterinary use as well as for human use. There is a separate biological products law, administered by the Agriculture Department, for veterinary biologicals, but the Federal Food, Drug, and Cosmetic Act applies to veterinary products as well as to items for human use.

A special section of the Federal Food, Drug, and Cosmetic Act requires that each batch of certain named antibiotics, and each batch of insulin, be tested and certified by the Food and Drug Administration. This is, of course, a very stringent requirement, and presumably it would not be practical for application to all drugs.

Fortunately, as Parke M. Banta observed in the Food-Drug-Cosmetic Law Journal, April 1958, "the law has been administered by scientists dealing with their counterpart scientists in the industry concerned and primarily by the medical scientific discipline common to both. * * * It is not a field for less than the expert. Perhaps nowhere in government is the objective of the manufacturer and of the regulating agency so near the same.

"A further illustration of the value of the cooperative relationships existing between the administrators of the law and the licensees is provided in the Asian influenza outbreak in 1957. While the work of the Army in isolating and identifying the new strain of influenza placed this country in a position, for the first time in history, to prepare in advance for an influenza epidemic, there remained the considerable task of developing promptly an effective vaccine in large quantities. Here the Public Health Service provided the seed material and worked on the scientific problems involved with those manufacturers that had previously been licensed to produce influenza vaccine involving other strains. A protective product was thus made available to the public in a much shorter time than would otherwise have been possible—a unique accomplishment in preparation for an influenza epidemic."

The manufacture and distribution of narcotics by the pharmaceutical industry is regulated by the Bureau of Narcotics. The implications of such regulation are international. Under some eight international conventions and protocols on the subject of narcotic drugs, the U.S. Government has accepted certain obligations to control the production and distribution of these drugs in such a manner that they will be available only for medical and scientific purposes.

Narcotic preparations are subject to a special tax law, administered by the U.S. Treasury Department. This law controls primarily the distribution of narcotics, instead of the strength, quality, and purity. Of course, narcotic preparations must meet the standards imposed by the Federal Food, Drug, and Cosmetic Act as well, and I believe the Commissioner of Narcotics could find a way to take legal action against a manufacturer not meeting requirements of strength, quality, and purity in his products.

The distribution of narcotic preparations is controlled to the ultimate purchaser by imposing a Federal tax stamp upon each final container. Each manufacturer, wholesaler, and retailer is registered by the Bureau of Narcotics and special forms, which are numbered, must be used in making transfers of narcotic products from one place to another.

The Commissioner of Narcotics has quite a lot to say about the quantity of narcotics produced and distributed in the United States. Since opium cannot legally be grown domestically, and since he controls the quantity imported, he

has a way of controlling very definitely the amount of narcotic preparations manufactured within U.S. boundaries. The law does not yet give the Commissioner of Narcotics the power to control the quantity of synthetic narcotics manufactured domestically, but the Karsten bill would give him this power legally. In the meantime, he exercises the power because of a voluntary allocation system in force between the Commissioner and each individual manufacturer of synthetic narcotics.

The field of control has become a relatively flexible one, extending to more products and more manufacturers as new synthetic narcotic drugs are developed and introduced into medicine. Control can no longer be limited to substances derived from crude opium or coca leaves. When a new synthetic narcotic drug is found to possess addiction liability similar, for instance, to that of morphine (as almost invariably has been the case up to the present), our Government is obliged to apply to this new drug the control provisions of the 1931 (international) convention.

The main part of this section has been devoted to a discussion of drug manufacturing controls. Closely connected to these controls are requirements on the legal distribution of prescription products, which are imposed by the Federal law and many State laws. The Federal Food, Drug, and Cosmetic Act relates that products bearing the prescription legend move in certain authorized channels of distribution, thus protecting the public by not making unusually potent preparations available without the supervision of a doctor. Each manufacturer must exercise extreme care in making sure that the prescription products he produces are sent only to authorized wholesalers, retailers, and other recipients. Here again, the manufacturer is subject to legal action if he violates these requirements, knowingly or unknowingly.

The Federal Food, Drug, and Cosmetic Act, and many other laws, also regulate the total quantity of each product within its own container. In other words, there are penalties for deceptive filling, slack filling, etc. Quantities of products in containers are carefully controlled by drug manufacturers to make sure that the customer receives his money's worth, and to comply with these requirements. Extra amounts are carried in containers of products which are expected to contain a stated number of doses, to allow for a few drops lost between fillings of hypodermic syringes, etc.

The requirements of the Federal Food, Drug, and Cosmetic Act, and other laws, are usually stated in general terms. Specific technical requirements and tests for individual drug products are described in the "United States Pharmacopeia" and "National Formulary," which are legally recognized books of standards. These books are not, however, compiled under the direction of the Government, but are private enterprises of U.S. citizens. Individual drug preparations described in the U.S.P. or N.F. must meet the standards of strength, quality, and purity as defined by these official compendia, and the manufacturer is subject to legal action if his products do not meet these standards. The general provisions of the law make this legal action possible, but the specific standards are almost always contained in the books themselves. In addition to U.S.P. and N.F. standards, the laws and regulations require that every product, whether contained in these books or not, must meet the standards of strength, quality, and purity named on its own label, or described in the new drug application for the particular product concerned.

It has always seemed to me that the ethical pharmaceutical industry has successfully lived with more regulatory controls than any other industry of comparable size, as far as I know. I realize that public utilities have extensive financial controls, but surely they do not have equivalent controls over the quality and safety of their products.

The industry has successfully met these stringent requirements through the years because of the amount of devoted effort given to quality and safety of products. I once heard a consulting engineer point out how many household appliances are defective in one way or another when the customer gets them. Of course, these defects are usually corrected within the guaranteed period. However, the pharmaceutical industry cannot tolerate even a tiny proportion of defective products, for obvious reasons.

Industry-Government cooperation, however, is not necessarily limited to that required by statute. During World War II, for example, industry and Government worked closely together for the common good. The development of a large-scale manufacturing method for penicillin furnishes an excellent illustration of wartime cooperation.

Reports of the unusual activity of penicillin resulting from the work of Florey and Heatley in England had already spurred exploratory work by some U.S. manufacturers when Florey visited the Northern Regional Research Laboratory of the Department of Agriculture, at Peoria, Ill. The laboratory started work immediately and subsequently met with the interested manufacturers to arrange some sort of coordinated research for increasing the production of penicillin. The Government's Committee on Medical Research (CMR) was to coordinate the results of their work and to arrange with the War Production Board so that they might receive priorities for the equipment of their laboratories and pilot plants.

By the time chemical procedures were fairly well standardized early in 1943, the War Production Board undertook to arrange for the priorities necessary to construct and equip the factories. The CMR was to continue its clinical evaluation of the drug and the experiments on structure and synthesis which were in progress. The Office of Production Research of the WPB agreed to support work in various universities in connection with technical improvements in production. The Defense Plant Corporation was to finance the small percentage of construction costs which some of the firms were unable to provide. The Food and Drug Administration of the Public Health Service assumed the testing of the firms' products which had previously been performed at Peoria. With this organization the program burgeoned.

There is little doubt that this cooperative effort assured the success of the penicillin program, most of which was actually financed and accomplished by private industry. And, as a result, a whole group of infectious diseases, previously not susceptible to specific treatment or ineffectively treated, was brought under control. Wherever the public interest has seemed to require it the pharmaceutical industry has wholeheartedly cooperated with the Government and this collaboration has in the past resulted in real benefits for the public health.

It may be fairly said that Government-industry relations have been those of freemen cooperating with free government in the public interest. The industry has itself shown a sense of responsibility for the public welfare which has, we believe, won the respect of those in Government who have had contact with it. Fortunately, the Government regulation required by statute has not interfered with the operation of a strong, free enterprise, competitive industry. Lack of Government interference or restraint in the economic operation of the industry has resulted in dynamic and dramatic growth with almost unparalleled contribution to the public welfare.

How Has the Pharmaceutical Industry's Progress Been Accomplished?

A report to Dr. Austin Smith, president, Pharmaceutical Manufacturers Association, by Donald B. Woodward and Banks T. Adams, Jr.

I. Summary of Conclusions

The evidence assembled herein indicates that the ethical drug manufacturing industry has had a rate of growth in dollar sales from 1947 through 1957 of 9.8 percent, compounded annually, and that this increase has been one of volume rather than a volume and price. The industry has historically required a little over $1 of gross tangible assets for each $1 of annual sales. Permanent capital to finance the expansion of assets required to enable the growth in sales has been primarily in the form of equity provided through retained earings. The industry's current ratio has had a level to declining trend over time and the percentage of cash and security assets to total current assets has shown no substantial permanent increase in the postwar years.

Three factors have been primarily responsible for enabling the industry to acquire the capital funds (mostly equity) used to finance past growth:

A good but competitive return on total invested capital, as well as on equity capital alone;

A reasonably good growth in net income; and

A payout of earnings in the form of dividends at a rate slightly above average.

Though the industry's profit margin and rate of return on total capital ratios are higher than those of a number of other industries, attention is called to the declining trend in these measures since the 1935–39 period and to the fact that these ratios have been simply in a competitive range. One major

reason for the postwar decline in these two profit-measuring yardsticks has been the increase in corporate taxation which now divides earnings about equally between the company and the Government. After a payout of earnings averaging a little more than 50 percent the industry retains but about 25 percent of pretax profits with which to finance future growth.

Research, dissemination of product information, administration, and cost of production have also been only that which was necessary to get the pharmaceuticals developed and distributed; the informational job has been especially large and complicated due to the rapid expansion in products, and the many thousands of doctors and druggists who must be kept informed in order to assure effective use.

Any greater reduction in profit margins and rate of return on capital than has occurred might well have curtailed the growth of output by limiting the amount of capital.

II. THE BASIC DATA

The principal ethical drug industry data utilized by this study consists of a tabulation of the financial statements reported by pharmaceutical manufacturing companies from 1947 to 1958 inclusive and have been assembled by the PMA staff. The tabulation includes all major ethical drug companies whose financial reports are published in Moody's Industrial Manual and/or for which annual statements were available: No unaudited data has been knowingly employed. The companies included are Abbott Laboratories; Allied Laboratories; Lakeside Laboratories; Eli Lilly; Mead Johnson; Merck, Sharp & Dohme; Parke, Davis; Pfizer; Smith Kline & French; and Upjohn. By comparison of the aggregate sales of these companies with estimated totals for the industry, it appears that this group has accounted for something like one-half of the industry's sales for the period under study.[1]

Material from other sources which have been used to complement and supplement these principal data are identified and described when used.

III. HOW HAS THE PHARMACEUTICAL INDUSTRY'S PROGRESS BEEN ACCOMPLISHED?

Over the past several decades the pharmaceutical manufacturing industry of the United States has made available to the medical profession, and through it to the people of the Nation and world a rapidly expanding array and volume of health-improving, life-extending, and pain-relieving products. In the postwar years alone manufacturers' sales have risen from about $500 million to almost $2 billion.[2] This dollar increase is made particularly significant by U.S. Department of Labor's wholesale price index, measuring the prices of drug and pharmaceuticals (and, through 1954 cosmetics). As table I on page — shows, the drugs and pharmaceutical group index has fallen actually since 1947 and in 1958 was only 94 percent of the base period 1947–49. The total wholesale price index, to the contrary, has moved upward 23.3 percent over the same period.

Clearly, then, if prices have not advanced, the growth in postwar sales must represent growth in physical volume. And, since production volume may be expected to bear a rather direct relationship to the need for assets to produce the goods, it follows that a growth of sales should be expected to be accompanied by an expansion of assets. It also follows that had funds not been available to finance the assets the production advances would not have been possible.

That the pharmaceutical products have reached the preponderant part of the U.S. population and an unmeasurable but significant part of the population of the earth is shown by a separate study.[3] And, the highly beneficial effect upon the population has also been authoritatively demonstrated.[4]

This study, therefore, attempts to show how this industry was able to achieve the production of such a growing amount of pharmaceutical products, and to assure their availability to doctors and their patients wherever and whenever needed. It also makes some comparisons with other industries.

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[1] Census of Manufacturers, U.S. Department of Commerce, with industry projections of same, and PMA data, table X herein.
[2] Census of Manufacturers, U.S. Department of Commerce, with industry projections of same.
[3] Reference: HIF paper.
[4] Reference: HIF paper.

Funds required

The pharmaceutical manufacturing industry now requires a little over a $1 of gross tangible assets to produce $1 of salable goods per year. (The ratio has ranged between a low of $0.85 and a high of $1.16 during the past 12 years, as shown in table IX. Thus, in order for the industry to supply $1 of additional medicine annually it must acquire approximately $1 of additional gross tangible assets. Table X shows that the PMA sample of 10 companies had an increase in sales from 1947 to 1958 of $763 million while gross tangible assets had to be increased by $984 million over the same years (table XI, p. 10754).

TABLE I.—*Wholesale price index*

[1947–49=100]

	All items	Drugs and pharmaceuticals [1]		All items	Drugs and pharmaceuticals [1]
1958	123.3	94.0	1952	112.4	92.5
1957	122.1	93.3	1951	115.0	95.6
1956	118.6	92.1	1950	104.1	92.5
1955	114.3	92.8	1949	100.3	93.6
1954	112.8	93.9	1948	103.9	101.0
1953	112.3	92.9	1947	95.8	105.3

[1] Also includes cosmetics through 1954. Source: U.S. Department of Labor.

The attraction of such sums from investors is a sizable task. Capital is scarce and timid: To be attracted it must have prospects of being reasonably rewarded, and with reasonable hopes of avoiding loss. The highly competitive pharmaceutical manufacturing business, with a record of many ventures showing severe losses as well as ventures showing gains, with various companies being heavily dependent on one or a few products, and with increasing amounts of research expenditure threatening existing products, certainly has risks of losses and consequently far from assurance of reasonable gains. The prospect and the hopes attaching to many companies other than drug manufacturers, during much of the period, have been judged by most investors to be superior, as demonstrated by the ratios of price of stocks to earnings.

Source of funds

How, then, has the industry raised the funds with which to purchase the assets required to make possible the large increase in output previously noted? A look at both the total capital and common equity capital position of the industry over time is most revealing. Table XI shows the figures. Total capital as calculated herein is the sum of all funds permanently invested (long-term debt, preferred stock, equity capital, reserves and minority interest less intangibles) and has increased by $612 million from 1947 to 1958. Common equity is simply net worth less intangibles (not including preferred stock) and over the same period has increased $588,000,000. The balance of the required increase in the gross tangible assets ($984 million) had to be provided by creditors and by the reserves (depreciation) established for asset replacement. Actually, the foregoing figures, particularly with respect to gross tangible assets, are probably understatements of the true increases required. This results from the fact that only net changes have been reflected with no account given to the writeoff of assets during these years.

From this data it can be concluded therefore, that over 95 percent of the net increase in permanent capital used in financing the postwar growth of the 10 companies has been provided by owners of the business—the common stockholder: $588 million of the $612 million required. Without question common equity funds have been the key factor in the industry's supply of capital.

Whether or not individual managements should or could have financed more heavily with senior securities is at best conjectural. It must be assumed that for numerous and independently arrived at reasons, managements for the respective companies have deemed it best to rely preponderantly upon equity financing. In a free enterprise economy such decisions are the responsibility of corporate managers.

Of the equity capital raised, most has been acquired through the retention of earnings rather than by stock flotations. This raises the immediate question

as to whether the capital so generated has been really needed to finance the growth in sales? To answer this question a review of the industry's current asset composition over time proves enlightening. Table II below has been constructed to show the percentage breakdown of the current assets owned by the industry at yearend of 1948, 1953, and 1958. It is based on the 10 company sample previously discussed.

Attention is specially called to two items in the table. First, the total quick assets category which is composed of cash and marketable securities: These assets have accounted for about 35 percent of total current assets in the three periods shown. No trend is evident. Secondly, it is important to note the stability in the industry's current ratio (current assets divided by current liabilities).

By relating these two observations it can be stated that:

(*a*) Profits which have been retained have not been used to build up nonoperating assets (cash and securities) disproportionate to the growth in total current assets; and

(*b*) a stable current ratio suggests that the permanent capital needed by the industry has been growing no more rapidly than necessary, because current liabilities have had to supply a rather constant portion of total funds used to finance current assets.

In conclusion, therefore, it appears that the portion of profits which have been retained have been no greater than the industry has required. Thus, on this basis it appears that profit margins have not been too high for the performance of the function of providing funds.

It may be argued hypothetically that the industry could have obtained equity capital by the sale of common stock in the market instead of relying chiefly on the retention of earnings. The fact is that the managements did not feel, in the circumstances of their operations, that this was desirable. The reasons which impelled managements to this conclusion could only be ascertained by extensive study. But the reasons evidently were persuasive, and it was management's responsibility to make the decisions.

TABLE II.—*Current asset position, 10 ethical drug manufacturers, 1948, 1953, and 1958*

	1948	1953	1958
Percent of total current assets:			
Total quick assets.....percent..	34.3	37.0	35.5
Cash.....do....	19.4	16.9	14.3
Securities.....do....	14.9	20.1	21.2
Accounts and notes receivable.....do....	18.0	19.0	25.6
Inventories.....do....	46.6	42.8	38.1
Other.....do....	1.1	1.2	0.8
Total.....do....	100.0	100.0	100.0
Current ratio.....	2.87:1	2.58:1	2.75:1
Quick assets to current liabilities.....	.99:1	.95:1	.98:1

Attraction of funds

Three factors have been significant in enabling this industry to acquire the capital funds which growth has required:

(*a*) a good but competitive return on total invested capital, as well as equity capital alone;

(*b*) a reasonably good growth in net income; and

(*c*) a payout of earnings in the form of dividends at a rate slightly above average.

Each of these will be discussed in subsequent pages.

Appraisal of the above statements requires information in two areas:

(1) What have been the trends in margins, rates of return, turnover, and profits?

(2) How does the rate of return, profit margin, turnover, and profit growth compare with other industries with which pharmaceutical manufacturers must compete for capital?

IV. RATES OF RETURN, PROFIT MARGINS, TURNOVER AND GROWTH IN PROFIT

Perhaps the most comprehensive body of material on comparative financial data for major U.S. industries is to be found in the Cottle and Whitman study of corporate earning power.[5] That work is relied upon quite heavily, in the remaining sections of this report, as a basis of comparison for the financial performance, over time, of the ethical drug industry. The ethical drug industry is represented by the PMA staff 10 company sample, previously referred to herein. It must be pointed out, however, that there are some variations between the methods employed by Cottle-Whitman and by the PMA staff. The PMA sample presents a compilation based on unadjusted data as it appears in various Moody's Industrial Manuals and company annual statements. The Cottle-Whitman work, however, undertook to adjust both the income statements and balance sheets of the sample companies. While the details of each such adjustment would be too voluminous to present herein, that task would appear to be obviated by the fact that both Dr. Cottle and the PMA staff are of the opinion that the studies possess sufficient similarity to render comparisons meaningful, particularly where period averages are concerned.

Trends in rate of return, margin, and turnover

Over the long term the pharmaceutical manufacturing industry has experienced some deterioration in the earning power on its total capital investment. And, perhaps of more importance is the fact that this long-term decline in rate of return would appear to be wholly attributable to a lower posttax profit margin. The turnover rate has fluctuated somewhat.

Though the PMA figures on this industry cover only the period since 1947, the Cottle and Whitman study provides a reasonably comparable series of data running from 1935 to 1955. Long-term movements in the rate of return, profit margin, and turnover have been developed by using both sources of data.

The rate of return on total capital fell drastically from the 1935–39 period to 1951–55 and so did the profit margin. From 1951–55 the industry was able to achieve improvement in both turnover and profit margin, and thus in the rate of return. But both rate of return and profit margin recovered only to about the level existing in the 1947–50 period. And, both ratios fell from 1957 to 1958.

	Rate of return on total capital (percent)	Posttax profit margin (percent)	Capital turnover times
Cottle-Whitman:			
1935–39	24.1	18.1	1.33
1947–50	19.6	12.6	1.56
1951–55	13.4	10.0	1.32
PMA staff:			
1951–55	13.6	10.5	1.30
1952–56	14.1	10.9	1.30
1956–58	19.1	13.3	1.43
1958	18.1	13.0	1.39

The Government's share

One significant factor which has contributed to the lower margin over time has been the rise in corporate tax rates. The prices which the industry has had to charge for its products, in order to finance the growth in the volume of pharmaceuticals contributing so much to health, life, and comfort, have been somewhat higher than would otherwise have been the case because of the large and growing amounts which have been paid to the Government. The following figures substantiate this statement:

	1958 as percent of 1947
Sales	252
Taxes	345
Reported net income	221

[5] Cottle, C. S., and Whitman, W. T., "Corporate Earning Power and Market Valuation 1935–55," Duke University Press, Durham, N.C., 1959.

The Government, in fact, has been taking since 1951 from the proceeds of sales each year about the same amount as the total earnings accruing to the stockholders (see table X, p. 10753). But while the stockholders have been ploughing back into the business about 50 percent of the amount earned for them, in order to **finance the growth of the business, all of the Government share has been withdrawn in cash.**

Industry comparison—Rate of return on total capital

In comparison to 32 other industry samples compiled by Cottle and Whitman, the ethical drug sample (PMA staff) had the seventh highest return on total capital for the 1951–55 period. (Table III, p. —.) The automobile, aircraft, proprietary drug, nonferrous metals groups, apparel and accessories chainstores, and automobile parts and accessories companies, exceeded the ethical drug figure of 13.6 percent. It is important to observe that while the ethical drug industry had a relatively high rate of return on total capital, it was definitely not a leader in this respect in the 1951–55 period. In fact, the most that can be said is that the rate of return on total capital achieved by the ethical drug manufacturers fell in an upper quadrant of a very competitive range of industries.

TABLE III.—*Average rate of return on total capital (earnings on total capital to total capital), 1951–55*

	Percent
Automobiles	21.9
Aircraft	19.1
Proprietary drugs	16.6
Nonferrous metal	14.7
Apparel and accessories chainstores	14.3
Automobile parts and accessories	13.7
Ethical drugs [1]	13.6
Building materials	13.2
Electrical supplies and equipment	13.0
Oil	12.4
Toilet preparations and soap	12.3
General industrial machinery	12.2
Corn products	12.0
Paper and allied products	12.0
Glass containers	11.9
Radio and television	11.7
Mail-order houses	11.0
Copper	10.9
Rubber	10.8
Chemicals	10.6
Packaged Foods	10.5
Steel	9.6
Dairy products	8.8
Grocery chainstores	8.7
Limited-price variety	8.7
Metal containers	8.4
Grain mill products	8.2
Cigarettes	7.8
Department stores	7.5
Agricultural machinery	7.4
Distilling	7.0
Textile fabrics	6.6
Meat packing	3.8

[1] PMA staff calculation, 10-company sample.

Source: Cottle and Whitman, "Corporate Earning Power," p. 19.

Comparative profit margins

With regard to profit margins the ethical drug figure (PMA sample) ranks third with a 1951-55 average of 10.5 percent: Copper with 15.1 percent and oil with 12 percent ranked Nos. 1 and 2. (Table IV below.) Here the spread between third place and a number of other industries which follow is not as small as in the case of the rate of return. However, there is definitely a wide gap between the copper and ethical drug figure.

TABLE IV.—*Average net profit margin (earnings available to total capital to sales), 1951-55*

	Percent
Copper	15.1
Oil	12.0
Ethical drugs[1]	10.5
Chemicals	9.5
Building materials	9.2
Paper and allied products	8.8
Proprietary drugs	7.8
Corn products	7.4
Automobiles	6.6
Steel	6.5
General industrial machinery	6.2
Glass containers	5.6
Electrical supplies and equipment	5.4
Toilet preparations and soap	5.3
Agricultural machinery	5.2
Automobile parts and accessories	4.7
Rubber	4.6
Mail-order houses	4.4
Cigarettes	4.4
Distilling	4.3
Metal containers	4.3
Limited-price variety	4.0
Textile fabrics	3.8
Radio and television	3.6
Packaged foods	3.4
Apparel and accessory chains	3.3
Aircraft	3.0
Department stores	2.8
Dairy products	2.7
Grain mill products	1.9
Grocery chain stores	1.0
Meat packing	.6
Nonferrous metals	(2)

[1] PMA staff calculations.
[2] Not available.

Source: Cottle and Whitman, "Corporate Earning Power," p. 30.

Comparative turnover of capital

With regard to capital turnover, however, the ethical drugs rank far down on the list—29th out of 32. And, it is in this regard that some surprising facts appear. The ethical drug industry has had a 1951–55 average capital turnover of 1.30 times. This means that sales have been 30 percent greater than total capital or that it has required $1 in total capital to support each $1.30 of sales. As its low ranking would indicate, pharmaceutical manufacturing is a rather high capital investment industry and can be compared with steel, building material, agricultural machinery, and paper and allied products (table V below).

TABLE V.—*Average rate of turnover of total capital (sales to total capital), 1951–55*

	Percent
Grocery chainstores	8.54
Meatpacking	6.41
Aircraft	6.29
Apparel and accessory chainstores	4.37
Grain mill products	4.22
Automobiles	3.33
Radio and television	3.28
Dairy products	3.28
Packaged foods	3.08
Automobile parts and accessories	2.93
Department stores	2.65
Grain mill products	2.50
Electrical supplies and equipment	2.42
Rubber	2.33
Toilet preparations and soap	2.32
Limited-price variety	2.16
Proprietary drugs	2.12
Glass containers	2.12
General industrial machinery	1.97
Metal containers	1.95
Textile fabrics	1.75
Cigarettes	1.75
Corn products	1.62
Distilling	1.61
Steel	1.48
Building materials	1.44
Agricultural machinery	1.43
Paper and allied products	1.36
Ethical drugs [1]	1.30
Chemicals	1.12
Oil	1.03
Copper	.72
Nonferrous metals	([2])

[1] PMA staff calculations.
[2] Not available.

Source: Cottle and Whitman, "Corporate Earning Power," p. 31.

More current industry comparisons

The Cottle & Whitman book for which material in tables III, IV, and V has been drawn, covers the years 1935–55. It is desirable to see what has occurred since then.

Figures for the earnings rate on total capital for the average of the period 1953–57 have been made public by the Stanford Research Institute, where Dr. Cottle is now located. These appear in table VI below, which is comparable to table III.

TABLE VI.—*Comparative industry earnings rates on total capital, average rate, 1953–57*

	Percent		Percent
Aircraft	21.3	Paper and allied products	11.3
Proprietary drugs	20.5	Mail-order houses	10.9
Automobiles	19.5	Steel	10.7
Apparel and accessory chains	14.6	Grocery chainstores	10.3
Ethical drugs	14.6	Rubber	10.2
Nonferrous metals	14.4	Chemical, excluding DuPont	10.1
Corn products	13.1	Dairy products	9.6
Chemical, including DuPont	13.0	Cigarettes	9.0
Auto parts and accessories	13.0	Radio and television	8.8
Building materials	12.8	Grain mill products	8.1
General industrial machinery	12.4	Limited-price variety	8.1
Oil	12.1	Metal containers	8.1
Glass containers	12.0	Department stores	7.9
Toilet preparations and soap	11.9	Distilling	6.2
Electrical supplies and equipment	11.8	Agricultural machinery	5.9
Copper	11.5	Textile fabrics	5.7
Packaged foods	11.4	Meatpacking	4.0

NOTE.—For this period substantially the same pattern and magnitudes appear as in table III.

Source: Stanford Research Institute.

To obtain the latest figures the PMA staff has selected the four highest industries from table III and has compiled samples exactly comparable in method to the ethical drug samples used herein. The results of this comparison are presented in table VII, page 15.

In the last several years the ethical drug industry has pulled ahead of the other four industries from the standpoint of return on total capital. The development would seem to result largely from two factors. Both 1957 and 1958 were affected by the general economic recession; a circumstance which, as was to be expected, would be most significantly reflected in the operating results of heavy goods producers which are three out of the four industries used in comparison. Secondly, these same years have been unusually favorable for some drug producers as a consequence of the prevalence of illnesses carried by old and new virus strains, etc.

The ethical drug industry nevertheless experienced a decline from 1957 to 1958 in both the profit margin and the turnover rate. Consequently, the rate of return on capital fell significantly from 1957 to 1958.

The 1957–58 period therefore appears to present an abnormal picture. The facts of the ethical drug industry are, when the evidence is examined for a sizable period of time, that:

(1) The rate of return on capital appears to have been declining irregularly for a long period of time,

(2) While the rate of return has customarily been in the higher segment of manufacturing industries, it has not over any average period been the highest,

(3) The spread between the rate of return in this industry and a large number of others has not been significant,

(4) The ethical drug industry return which was unusually stimulated in 1957 by the prevalence of respiratory infections, and increased demand for other products, fell again in 1958, while most other industries were depressed by economic recession in 1957–58.

To this it should be added that the rate of return would be expected to be high for an industry so marked by innovation and expansion as the ethical drug industry, and by the risk provided by very large research working which makes product obsolescence extremely rapid.

Rates of growth in net income

Comparative rates of growth in net income for the 10 years 1947–57 have been calculated for the aggregate of a large number of industries. The net income figures were taken from Moody's Industrial Manual, 1958, "Special Features Section" and the growth trends were computed using the "least squares" statistical method. The growth rates, therefore, are completely independent of any base year.

TABLE VII.—*Return on total capital comparisons for 5 manufacturing industries with highest average return in 1951–55, years 1956, 1957, and 1958 and average for 1956–58*

	Percent
1958:	
Ethical drug	18.1
Apparel and accessory chains	13.4
Aircraft	10.2
Automobiles	9.3
Nonferrous metals	7.1
1957:	
Ethical drug	20.4
Aircraft	15.3
Apparel and accessory chains	15.2
Automobiles	14.8
Nonferrous metals	14.0
1956:	
Ethical drug	18.8
Nonferrous metals	17.4
Aircraft	16.3
Automobiles	14.3
Apparel and accessory chains	14.3
1956–58 average:	
Ethical drug	19.1
Apparel and accessory chains	14.3
Aircraft	13.5
Automobiles	12.7
Nonferrous metals	12.6

The 10-year growth rates range from 29 percent compounded p.a. for aircraft to —1.1 percent for the insurance industry sample. Ethical drugs exhibited a rate of 6.2 percent (table VIII below).

On the basis of these comparisons it is concluded that the subject industry has displayed a reasonably good growth in net income, but not so rapid as a number of other industries.

TABLE VIII.—*Rates of growth in net income*

	Number of companies in sample	10 year growth rate (1947–57) (percent)
Aircraft and parts	16	29.0
Airlines	6	28.1
Sales finance	5	14.7
Machine tools	5	14.4
Electronics miscellaneous	11	13.7
Air-conditioning	4	13.0
Aluminum	4	11.7
Cement	7	10.7
Petroleum (integrated)	10	9.9
Refractories	2	9.5
Rubber and tires	4	9.3
Steel	13	9.1
Chemicals	22	8.7
Automobiles and trucks	8	7.2
Machinery, miscellaneous	21	7.2
Paint and flat glass	4	6.9
Drugs—proprietary	5	6.9
Machinery—office equipment	7	6.7
Paper and paperboard	10	6.6
Member banks (Federal Reserve System)		6.4
Electrical equipment	9	6.2
Metals—fabricating	6	6.2
Other nonferrous metals	10	4.7
Electronics—radio and television	7	4.2
Copper	3	3.6
Petroleum producers	4	3.0
Building materials and supplies	15	2.6
Insurance	10	—1.1
Ethical drugs	10	6.2

Source: Piedmont Advisory Corp. study.

Prospects of dividends

A third factor which has enabled this industry to attract equity capital has been the willingness of management to pay out in dividends at a rate slightly above average. The facts are shown below:

Payouts of earnings available to common stock equity

[Percent]

	Composite industry performance	PMA 10 company ethical drug sample		Composite industry performance	PMA 10 company ethical drug sample
1947	42	43	1954	53	60
1948	37	39	1955	48	53
1949	48	48	1956	N.A.	50
1950	47	48	1957	N.A.	50
1951	51	53	1958	N.A.	55
1952	54	65	1951–55 average	51	58
1953	52	62			

V. RESEARCH, PRODUCTION, AND EDUCATION

In order to provide the growing volume of beneficent products, which fortunately for the general welfare the industry has been able to do, other costs have had to be covered in addition to payments to the Government and provision of necessary new capital—though, to repeat, it must always be remembered that capital is essential if production is to occur. The other costs are those of production, research, dissemination of product information, and administration.

Little need be said here, presumably, of research, production, and administration. Rapidly growing amounts have been spent on research and the results fully warrant the expense. A high obsolescence rate in products is a characteristic of this industry, and is a factor which requires an ever increasing research program if a competitive position is to be maintained. Cost of production is obviously an essential expense, and vigorous efforts have been made to hold it to a minimum by constant efforts to improve methods, and large outlays for new equipment to make production more efficient. Administration is a necessary feature of any business operation.

The expenses for disseminating information about new drugs are a less well understood item. But this activity is a necessary and highly significant part of the industry's great service to the public. If the industry's products are to be used by doctors to improve the health of their patients, the doctors must become acquainted with them very fully. And, if the doctors are satisfied, and wish their patients to use the products, the prescriptions must be filled; this means that the Nation's druggists must be acquainted with the products.

This educational or informational activity is carried on by the manufacturers. Without it, research and production would be futile.

TABLE IX.—*Ethical drug industry, 10-company sample[1] return on investment ratios, 1947–58*

	Common stock equity			Total capital			Gross tangible assets		
	Rate of return	Post-tax profit margin[2]	Turnover of equity	Rate of return	Post-tax profit margin[3]	Turnover of capital	Rate of return	Post-tax profit margin[4]	Turnover of assets
	Percent	*Percent*	*Times*	*Percent*	*Percent*	*Times*	*Percent*	*Percent*	*Times*
1958	19.3	12.9	1.50	18.1	13.0	1.39	11.6	13.0	0.89
1957	22.0	13.6	1.61	20.4	13.8	1.48	13.0	13.8	.94
1956	20.7	12.9	1.61	18.8	13.1	1.43	12.2	13.1	.93
1955	17.2	10.9	1.59	15.1	11.2	1.35	10.2	11.2	.91
1954	14.2	9.5	1.50	12.2	9.9	1.23	8.4	9.9	.85
1953	13.4	8.9	1.51	11.4	9.4	1.22	7.9	9.3	.85
1952	14.0	9.3	1.50	12.3	9.8	1.25	8.5	9.8	.86
1951	19.4	11.5	1.68	17.6	11.8	1.49	11.6	11.8	.99
1950	23.0	14.6	1.57	21.3	14.9	1.44	14.9	14.8	1.00
1949	22.5	14.2	1.59	20.3	14.6	1.39	14.4	14.6	.99
1948	27.5	15.2	1.80	23.7	15.7	1.51	16.6	15.5	1.07
1947	28.8	14.6	1.98	25.4	15.0	1.70	17.2	14.9	1.16
Average:									
1951–55	15.6	10.0	1.55	13.6	10.5	1.30	9.3	10.4	.89
1952–56	16.1	10.4	1.54	14.1	10.9	1.30	9.6	10.8	.89
1956–58	20.6	13.1	1.57	19.1	13.3	1.43	12.3	13.3	.92

[1] Sample composed of: Abbott Labs., Allied Labs., Lakeside Labs., Lilly (Eli), Mead-Johnson, Merck (Sharp & Dohme), Parke Davis, Pfizer, Smith Kline & French, Upjohn.
[2] Based on reported net income after preferred stock dividends.
[3] Based on reported net income (before preferred dividends) with interest on long-term debt added back after adjustment for corporate taxes.
[4] Based on reported net income.

TABLE X.—*Ethical drug industry, 10-company sample income statement, 1947–58*

[Thousands]

	Net sales	Cost of goods	Selling, administrative, and general	Operating profits	Other income, net	Pretax profits	Total taxes	Reported net income	Preferred dividends	Net income to common equity	Common dividends	Net income to total capital
1958	$1,263,492	$489,112	$467,835	$306,546	$14,565	$321,112	$156,821	$164,289	$1,692	$162,597	$89,029	$164,540
1957	1,200,651	459,383	421,824	319,451	13,752	333,203	167,281	165,921	2,111	163,810	81,507	166,220
1956	1,055,338	422,188	361,667	271,482	8,614	280,096	141,816	138,281	2,470	135,811	67,465	138,481
1955	933,049	401,970	321,919	209,160	3,454	212,614	107,948	104,664	3,357	101,307	54,070	104,860
1954	822,914	372,920	289,990	160,003	(1,327)	158,676	77,387	81,289	3,376	77,913	46,884	81,716
1953	797,500	392,853	251,128	153,515	(769)	152,745	78,819	73,927	3,182	70,745	43,854	74,657
1952	768,928	390,105	230,578	148,249	4,113	152,365	77,353	75,012	3,404	71,608	46,795	75,680
1951	776,800	364,667	201,485	220,649	3,706	224,355	133,000	91,355	1,947	89,408	47,616	91,550
1950	642,942	303,672	166,253	173,014	3,370	176,378	80,988	95,390	1,361	94,029	45,181	95,528
1949	566,865	281,591	150,533	134,743	(1,672)	133,074	50,572	82,500	1,985	80,515	38,260	82,879
1948	548,678	272,867	137,277	138,533	(1,755)	136,778	51,464	85,312	1,644	83,668	32,510	85,908
1947	500,637	256,899	122,893	120,845	(1,048)	119,797	45,405	74,391	1,523	72,868	31,218	74,994

TABLE XI.—*Ethical drug industry, 10-company sample, investment position, 1947–58*

[In thousands of dollars]

	Average common equity	Average total capital	Average gross tangible assets
1958	$841,401	$906,914	$1,416,594
1957	746,049	813,973	1,272,014
1956	656,761	737,302	1,132,012
1955	587,730	693,363	1,022,453
1954	548,313	671,636	963,077
1953	529,681	653,052	933,646
1952	512,760	613,352	897,132
1951	461,226	520,716	784,683
1950	409,229	447,518	642,168
1949	357,574	409,075	573,542
1948	304,226	362,632	515,029
1947	253,098	295,090	433,057

TABLE XII.—*Ethical drug industry, 10-company sample, profit margin and payout ratios, 1947–58*

	Operating profit margin [1]	Pretax profit margin	Posttax profit margin	Payout of earnings available to common stock equity
	Percent	*Percent*	*Percent*	*Percent*
1958	24.3	25.4	13.0	54.7
1957	26.6	27.8	13.8	49.8
1956	25.7	26.5	13.1	49.7
1955	22.5	22.9	11.2	53.4
1954	19.4	19.2	9.9	60.2
1953	19.2	19.2	9.3	62.0
1952	19.3	19.8	9.8	65.4
1951	28.4	28.9	11.8	53.3
1950	26.9	27.4	14.8	48.1
1949	23.8	23.5	14.6	47.9
1948	25.2	24.9	15.5	38.9
1947	24.1	23.9	14.9	42.8

[1] After depreciation.

APPENDIX A. COMPOSITION OF SAMPLES

ETHICAL DRUG MANUFACTURERS—10 COMPANY SAMPLE

Abbott Laboratories
Allied Laboratories
Lakeside Laboratories
Lilly (Eli)
Mead-Johnson
Merck (Sharp & Dohme)
Parke, Davis
Pfizer
Smith Kline & French
Upjohn

INDUSTRY SAMPLES—RETURN ON INVESTMENT COMPARISONS

Agricultural machinery industry:
- Allis-Chalmers Manufacturing Co.
- Case (J.I.) Co.
- Deere & Co.

Aircraft industry:
- Boeing Airplane Co.
- Chance Vought Aircraft Corp.[1]
- Consolidated Vultee Aircraft Corp.[2]
- Curtiss-Wright Corp.
- Douglas Aircraft Co., Inc.
- General Dynamics Corp.
- Lockheed Aircraft Corp.
- North American Aviation, Inc.
- United Aircraft Corp.

Apparel and accessories chain stores:
- Bond Stores, Inc.
- Grayson-Robinson Stores, Inc.
- Lerner Stores Corp.
- J. C. Penney Co.

Automobile industry:
- Chrysler Corp.
- General Motors Corp.

Automobile parts and accessories industry:
- Bendix Aviation Corp.
- Borg-Warner Corp.
- Dana Corp.
- Doehler-Jarvis Corp.[3]
- Eaton Manufacturing Co.
- The Electric Auto-Lite Co.
- Rockwell Spring & Axle Co.[4]
- Standard Steel Spring Co.[4]
- Stewart-Warner Corp.
- Thompson Products, Inc.
- The Timken-Detroit Axle Co.[4]

Building materials industry:
- The Flintkote Co.
- Johns-Manville Corp.
- National Gypsum Co.
- The Ruberoid Co.
- U.S. Gypsum Co.

Chemical industry:
- Allied Chemical & Dye Corp.
- American Cyanamid Co.
- The Dow Cemical Co.
- E. I. du Pont de Nemours & Co.
- Hercules Powder Co.
- Monsanto Chemical Co.
- Union Carbide & Carbon Co.

Cigarette industry:
- The American Tobacco Co.
- Liggett & Myers Tobacco Co.
- R. J. Reynolds Tobacco Co.

Copper industry:
- The Anaconda Co.
- Kennecott Copper Corp.
- Phelps Dodge Corp.

Corn products industry:
- Corn Products Refining Co.
- Penick & Ford, Ltd., Inc.

Dairy products industry:
- The Borden Co.
- National Dairy Products Corp.

Department stores:
- Allied Stores Corp.
- Associated Dry Goods Corp.
- City Stores Co.
- Federated Department Stores, Inc.
- Gimbels Bros., Inc.
- R. H. Macy & Co., Inc.
- Marshall Fields & Co.
- The May Department Stores Co.

Distilling industry:
- Distillers Corp.—Seagrams, Ltd.
- National Distillers Products Corp.
- Schenley Industries, Inc.
- Hiram Walker—Gooderham & Worts, Ltd.

Electrical supplies and equipment industry:
- General Electric Co.
- Westinghouse Electric Corp.

General Industrial machinery and equipment industry:
- American Chain & Cable Co., Inc.
- Blaw-Knox Co.
- Combustion Engineering, Inc.
- Fairbanks, Morse & Co.
- Ingersoll-Rand Co.
- Link-Belt Co.
- Worthington Corp.

Glass container industry:
- Anchor-Hocking Glass Corp.
- Hazel-Atlas Glass Co.
- Owens-Illinois Glass Co.

Grain mill products industry:
- General Mills, Inc.
- Pillsbury Mills, Inc.

[1] Formed in 1954 by United Aircraft's spinoff of its Chance Vought Division.
[2] Merged with General Dynamics Corp. on April 30, 1954; General Dynamics included only in 1954 and 1955.
[3] In 1952 merged with National Lead Co.
[4] In 1953 Standard Steel Spring Co. and Timken-Detroit Axle Co. consolidated to form Rockwell Spring & Axle Co.

Grocery chainstores:
- American Stores Co.
- First National Stores, Inc.
- The Kroger Co.
- Safeway Stores, Inc.

Limited-price variety stores:
- W. T. Grant Co.
- S. S. Kresge Co.
- S. H. Kress & Co.
- G. C. Murphy Co.
- F. W. Woolworth Co.

Mail-order houses:
- Montgomery Ward & Co., Inc.
- Sears, Roebuck & Co.

Meatpacking industry:
- Armour & Co.
- The Cudahy Packing Co.
- Swift & Co.
- Wilson & Co., Inc.

Metal container industry:
- American Can Co.
- Continental Can Co., Inc.

Nonferrous metals industry—excluding copper:
- The American Metal Co., Ltd.
- The American Smelting & Refining Co.
- The International Nickel Co. of Canada, Ltd.

Oil industry:
- Gulf Oil Corp.
- Phillips Petroleum
- Shell Oil Co.
- Socony Mobile Co., Inc.
- Standard Oil Co. of California
- Standard Oil Co. (Indiana)
- Standard Oil Co. (New Jersey)
- The Texas Co.

Packaged foods industry:
- General Foods Corp.
- Standard Brands, Inc.

Paper and allied products industry:
- The Champion Paper & Fibre Co.
- Container Corp. of America

Paper and allied products—Continued
- Crown Zellerbach Corp.
- International Paper Co.
- Kimberly-Clark Corp.
- Marathon Corp.
- The Mead Corp.
- Rayonier, Inc.
- St. Regis Paper Co.
- Scott Paper Co.
- Union Bag & Paper Corp.
- West Virginia Pulp & Paper Co.

Proprietary drug industry:
- American Home Products Corp.
- Sterling Drug, Inc.
- Vick Chemical Co.

Radio and television industry:
- Admiral Corp.
- Motorola, Inc.
- Philco Corp.
- Radio Corp. of America
- Sylvania Electric Products, Inc.

Rubber industry:
- Firestone Tire & Rubber Co.
- B. F. Goodrich Co.
- The Goodyear Tire & Rubber Co.
- U.S. Rubber Co.

Steel industry:
- Bethlehem Steel Corp.
- Inland Steel Co.
- Jones & Laughlin Steel Corp.
- National Steel Corp.
- Republic Steel Corp.
- United States Steel Corp.

Textile fabric industry:
- Burlington Industries, Inc.
- Cannon Mills Co.
- M. Lowenstein & Sons, Inc.
- Pacific Mills
- J. P. Stevens & Co., Inc.
- United Merchants & Manufacturers, Inc.

Toilet preparations and soap industry:
- Colgate-Palmolive Co.
- The Procter & Gamble Co.

INDUSTRY SAMPLES—EARNINGS GROWTH RATE COMPARISONS

Sales finance:
- Associates Investment Co.
- C.I.T. Financial Corp.
- Commercial Credit Co.
- General Motors Acceptance Corp.
- Pacific Finance Corp.

Electronics-miscellaneous:
- Beckman Instruments, Inc.
- Collins Radio Co.
- Consolidated Electro-Dynamics Corp.
- General Precision Equipment Corp.
- Hazeltine Corp.
- Minneapolis-Honeywell Regulator Co.
- Raytheon Manufacturing Co.
- Sperry Rand Corp.
- Sprague Electric Co.
- Sylvania Electric Products, Inc.
- Texas Instruments, Inc.

Air Conditioning:
- Carrier Corp.
- Fedders-Quigan Corp.
- Tecumseh Products Co.
- Trane Co.

Aluminum:
- Aluminum, Ltd.
- Aluminum Co. of America
- Kaiser Aluminum & Chemical Corp.
- Reynolds Metals Co.

Cement:
- Alpha Portland Cement Co.
- General Portland Cement Co.
- Ideal Cement Co.
- Lehigh Portland Cement Co.
- Lone Star Cement Corp.
- Penn-Dixie Cement Corp.
- Permanente Cement Co.

Integrated Petroleum Products:
- Gulf Oil Corp.
- Phillips Petroleum Co.
- Pure Oil Co.
- Shell Oil Co.
- Skelly Oil Co.
- Standard Oil Co. of California
- Standard Oil Co. (N.J.)
- Sunray Mid-Continent Oil Co.
- Texas Co.
- Union Oil Co. of California

Rubber and tires:
- Firestone Tire & Rubber Co.
- Goodrich (B.F.) Co.
- Goodyear Tire & Rubber Co.
- United States Rubber Co.

Steel:
- Acme Steel Co.
- Allegheny Ludlum Steel Corp.
- Armco Steel Corp.
- Bethlehem Steel Corp.
- Colorado Fuel & Iron Corp.
- Crucible Steel Co.
- Inland Steel Co.

Steel—Continued
- Jones & Laughlin Steel Corp.
- National Steel Corp.
- Republic Steel Corp.
- United States Steel Corp.
- Wheeling Steel Corp.
- Youngstown Sheet & Tube Co.

Chemicals:
- Air Reduction Co., Inc.
- Allied Chemical Corp.
- American Cyanamid Co.
- American Potash & Chemical Corp.
- Atlas Powder Co.
- Columbian Carbon Co.
- Commercial Solvents Corp.
- Dow Chemical Co.
- Du Pont (E.I.) de Nemours & Co.
- Food Machinery & Chemical Corp.
- Freeport Sulphur Co.
- General Aniline & Film Corp.
- Hercules Powder Co.
- Hooker Chemical Corp.
- Koppers Co., Inc.
- Monsanto Chemical Co.
- Olin Mathieson Chemical Corp.
- Pennsalt Chemicals Corp.
- Texas Gulf Sulphur Co.
- Union Carbide Corp.
- United Carbon Co.
- Victor Chemical Works.

Autos and trucks:
- American Motors Corp.
- Chrysler Corp.
- Diamond T Motor Car Co.
- Ford Motor Co.
- General Motors Corp.
- Mack Trucks, Inc.
- Studebaker-Packard Corp.
- White Motor Co.

Machinery—miscellaneous:
- American Chain & Cable Co., Inc.
- American Machine & Foundry Co.
- Babcock & Wilcox Co.
- Blaw-Knox Co.
- Bucyrus-Erie Co.
- Caterpillar Tractor Co.
- Chain Belt Co.
- Chicago Pneumatic Tool Co.
- Combustion Engineering, Inc.
- Dresser Industries, Inc.
- Fairbanks, Morse & Co.
- Gardner-Denver Co.
- Ingersoll-Rand Co.
- Joy Manufacturing Co.
- Link-Belt Co.
- Mesta Machinery Co.
- National Supply Co.
- Northwest Engineering Co.
- United Engineering & Foundry Co.
- United Shoe Machinery Corp.
- Worthington Corp.

Source: Cottle, C. S., and Whitman, W. T., "Corporate Earning Power and Market Valuation, 1935–55." Duke University Press, Durham, N.C., 1959, pp. 6–7.

Paint and flat glass:
- Devoe & Raynolds Co., Inc.
- Libbey-Owens-Ford Glass Co.
- Pittsburgh Plate Glass Co.
- Sherwin-Williams Co.

Proprietary drugs:
- American Home Products Corp.
- Bristol-Myers Co.
- McKesson & Robbins, Inc.
- Sterling Drug (Inc.)
- Vick Chemical Co.

Office machinery:
- Addressograph-Multigraph Corp.
- Burroughs Corp.
- International Business Machines Corp.
- National Cash Register Co.
- Royal McBee Corp.
- Smith-Corona, Inc.
- Underwood Corp.

Paper and paperboard:
- Champion Paper & Fibre Co.
- Container Corp. of America
- Crown Zellerbach Corp.
- International Paper Co.
- Kimberly-Clark Corp.
- Mead Corp.
- St. Regis Paper Co.
- Scott Paper Co.
- Union Bag-Camp Paper Corp.
- West Virginia Pulp & Paper Co.

Electrical equipment:
- Cutler-Hammer, Inc.
- Emerson Electric Manufacturing Co.
- Federal Pacific Electric Co.
- General Electric Co.
- I.T.E. Circuit Breaker Co.
- McGraw Edison Co.
- Reliance Electric & Engineering Co.
- Square D Co.
- Westinghouse Electric Corp.

Metal fabricating:
- Anaconda Wire & Cable Co.
- Bridgeport Brass Co.
- General Cable Corp.
- Mueller Brass Co.
- Revere Copper & Brass, Inc.
- Scoville Manufacturing Co.

Other nonferrous:
- American Metal Co., Ltd.
- American Smelting & Refining Co.
- Climax Molybdenum Co.
- Eagle-Picher Co.
- Hudson Bay Mining & Smelting Co., Ltd.
- International Nickel Co. of Canada, Ltd.
- New Jersey Zinc Co.

Other nonferrous—Continued
- Noranda Mines, Ltd.
- St. Joseph Lead Co.
- U.S. Smelting, Refining & Manufacturing Co.

Electrical-Radio and TV:
- Emerson Radio & Phonograph Corp.
- Hoffman Electronics Corp.
- Magnavox Co.
- Motorola, Inc.
- Philco Corp.
- Radio Corp. of America
- Zenith Radio Corp.

Copper:
- Anaconda Co.
- Kennecott Copper Corp.
- Phelps Dodge Corp.

Fertilizer:
- American Agricultural Chemical Corp.
- International Minerals & Chemical Corp.
- Tennessee Corp.
- Virginia-Carolina Chemical Corp.

Domestic oil producers:
- Amerada Petroleum Corp.
- Continental Oil Co.
- Ohio Oil Co.
- Seaboard Oil Co. (Del.)

Building material supplies:
- American Radiator & Standard Sanitary Corp.
- Bestwall Gypsum Co.
- Celotex Corp.
- Crane Co.
- Fibreboard Paper Products Corp.
- Flintkote Co.
- Holland Furnace Co.
- Johns-Manville Corp.
- Masonite Corp.
- National Gypsum Co.
- Otis Elevator Co.
- Ruberoid Co.
- U.S. Gypsum Co.
- U.S. Pipe & Foundry Co.
- Yale & Towne Manufacturing Co.

Insurance:
- Aetna Insurance Co.
- Continental Insurance Co.
- Fidelity-Phenix Fire Insurance Co.
- Glens Falls Insurance Co.
- Great American Insurance Co.
- Hartford Fire Insurance Co.
- Home Insurance Co.
- Insurance Co. of North America
- St. Paul Fire & Marine Insurance Co.
- U.S. Fidelity & Guaranty Co.

COMPETITION AND PROFITS IN THE ETHICAL DRUG INDUSTRY

Statement by Frederick L. Thomsen, Ph. D., consulting economist,
Pharmaceutical Manufacturers Association

Mr. Chairman and members of the committee, Senator Kefauver, in the opening session of these hearings on the ethical drug industry you stated that: "What in essence the subcommittee is seeking to determine is whether the public is adequately protected by competition."

Since then, many witnesses have testified, and your staff has inserted in the record a number of interesting exhibits. It has seemed to me, in studying the record, that many of the points brought out have been left hanging in the air, so to speak. The time has come to pull together some of the economic facts that have been presented, together with their implications in terms of the objectives of this committee as stated by you, and to view them dispassionately within the context of an orderly consideration of conditions of competition in the industry. This is the task that I have been asked by Dr. Smith to do.

But since I am testifying in a professional capacity, the committee may wish to have a summary of my professional training and experience.

I received my Ph. D. in economics from the University of Wisconsin, have taught economics at several colleges and universities, and have held a number of professional and administrative positions in the field of economic research with special emphasis on marketing and price analysis. I am the author of several widely used textbooks in those fields and am now engaged in writing a text on industrial prices. I have been professor of marketing at the University of Missouri; associate head of the Division of Statistical Research of the former Bureau of Agricultural Economics responsible for price analyses and the price situation and outlook reports of the Department of Agriculture; Director of the Marketing Research Branch, Production and Marketing Administration, USDA; and director of research for a New York City consulting firm which specialized in price analyses. Since 1952 I have been engaged in private consulting work, with headquarters in St. Petersburg, Fla. In the course of this work I have conducted a number of research projects in drug and medical fields.

I have been very much interested in the work of this committee not only in my capacity as a consulting economist but also as a resident of St. Petersburg, Fla., where, as you know, many retired people live on comparatively small fixed incomes, which makes prices of everything, including drugs, of special interest to them during a period of continuing inflationary trends Despite the warm sunshine and salubrious climate so frequently extolled by our Florida chambers of commerce, which I can personally testify do contribute to health and a general feeling of well-being, some of these older folks sometimes require drugs, and I can assure you that the deliberations of your committee have been observed with widespread interest in my adopted State.

In my testimony I will make no attempt to particularize the virtues of the tremendously important research and resulting new health-giving products of the ethical drug industry, although economists are said to delight in particularizing the obvious. This subject has been covered well and rather fully by other witnesses. Instead, I would like to deal directly and solely with the economic questions of competition, prices, and profits.

I. COMPETITION IN THE ETHICAL DRUG INDUSTRY

In considering the nature of competition in the ethical drug industry, let us first see who the competitors are. From the testimony that has been offered, one might get the impression that the industry is composed of only a few large firms. Actually, according to the 1954 census, there are 1,255 companies primarily engaged in the manufacture of drugs and medicines. Most of these firms produce ethical drugs and those which do not are potential producers.

A. CONCENTRATION

Ethical drug manufacturers are of widely varying size and compete in different fields, hence have different facilities and functions. Nevertheless, virtually all of them are either competitors or potential competitors of any other firm. There have been instances of small firms getting into the production of a successful drug product, changing the whole course of manufacturing and financial operations of the firm and putting it into more direct competition with others

previously predominant in the particular field involved. There has been a marked tendency on the part of chemical companies and manufacturers of proprietary drugs to enter the ethical drug manufacturing field in recent years.

The relative size or concentration of firms composing the industry is indicated by a report of the National Conference Board.[1] It states that: "Study of standard first 4, 8, and 20 company census-based concentration ratios for the 1947–56 period gives little cause for concluding * * * that concentration in drugs and medicines has become a major economic problem." For pharmaceutical preparations, which account for about 80 percent of total shipments of the drug manufacturing industry (both as defined by the Census Bureau), the share of industry shipments accounted for by the first 4 companies declined from 28 to 25 percent between 1947 and 1956; for the first 8 companies, it remained constant at 44 percent; and for the first 20 companies, it rose from 63 to 72 percent.

These figures indicate that among the top 20 companies (in volume) the smaller companies grew at a relatively faster rate.

The NICB study further states: "With a concentration ratio of 25 percent for the first four companies, the pharmaceutical preparations industry ranked close to the lowest quartile of all industries in size of concentration ratio. Indeed, 300 of the 447 manufacturing industries had higher ratios and 8 others had the same concentration ratio for the first 4 companies in that year (1954)."

Given the situation described without any industry identification, I believe that most economists would conclude that a broader basis for vigorous competition exists here than in many or even most American industries.

B. Forms of competition

Competition as it exists throughout most of American industry and commerce today under the free enterprise system takes three different forms:

(1) "Price competition," which is the attempt to increase earnings by increasing sales through lowering prices, or to increase earnings by raising prices. Such price changes may affect sales of an individual firm in either or both of two ways:

(*a*) By affecting the total consumption of the product by ultimate users;

(*b*) by affecting the proportion of total sales obtained by the individual firm.

(2) "Utility competition," which includes all kinds of research and development intended to expand total demand for the products produced by the firm, or its products relative to that of competitors, by enhancing the usefulness of the products.

(3) "Distribution competition," which includes obtaining wide physical availability of the product, advertising, personal selling, education, and a variety of other services, such as the extension of credit.

So far as the seller is concerned, these three forms of competition are interchangeable. All are designed to have the same effect, that is, to increase the net revenue of the firm by increasing sales at the existing or a lower price or permitting the same sales at a higher price. Each of these forms of competition has a cost to the competitor. Viewed from the standpoint of the individual firm, a decrease in price, an increase in research expenditures to improve the utility of the product, or an increase in distribution expenditures, represent a "cost." The decision as to which form to use in a given case depends upon the anticipated effect of the cost increase upon sales and the net revenue of the seller.

From a social standpoint, also, there is no special or peculiar merit to any one of these forms of competition. It is quite erroneous, for example, to view price competition as the only or even a particularly desirable form, as seems to be implied by some of the statements that have been made in the course of this committee's deliberations. Depending upon the circumstances, it is often more advantageous to the public for a manufacturer to incur a given competitive cost in the form of an expenditure for "utility competition" than as a "cost" to him of lowering the price per unit charged for the product. To dwell upon price as the only or even the main benefit that consumers obtain from competition is to overlook the most important advantages that the public has derived from com-

[1] An unpublished supplement, dated Feb. 17, 1960, to its broader published study entitled "Concentration Patterns in Manufacturing, Studies in Business Economics, No. 65, 1959." Interpretations of both absolute levels of the ratios cited and their trends over time are subject to the limitations set forth in this study.

petition. If this were not so, we would still be driving Model T Fords and using Model T drugs.

Let us suppose, for example, that at the end of World War II the leading firms of the drug industry had been run by executives of limited vision out to grab as much of the prevailing market for existing products as they could get, solely by cutting prices, while holding their expenses for research and distribution to a minimum. Under these conditions, prices of some drugs might have been lower during the intervening years than they were. However, the emphasis on price competition would have precluded the vast expenditures for research and distribution which were made during the intervening years, and we would today be lacking the benefits of hundreds of important new drug products that have played such a large part in the reduction of disease and extension of the life span during these decades.

Can there by any doubt that the general public has benefited much more from the fact that competition in the drug industry has taken partly the form of utility and distribution competition, rather than wholly price competition?

Let us suppose that at the end of the war the drug industry had been treated as a public utility, with prices and profits regulated on the basis of direct production costs, plus a limited profit, on drugs then being produced.

I shudder to think, having reached the age at which longevity has a special appeal, of how many diseases I might now be liable to incur without any suitable drug therapy and with a correspondingly dismal prognosis.

To say that any one of these three forms of competition is superior to the others, or that it is more a measure of the vigor of competition existing in an industry, or that it is productive of greater social benefits, is completely erroneous.

Nothing in what has been said about the great benefits derived by the public from utility and distribution competition should be interpreted to imply that there has been any lack of price competition in the industry. The history of the drug manufacturing industry bears striking evidence of the existing of price competition. Various witnesses in these hearings have brought out the fact that wholesale drug prices have not increased as much as (*a*) industrial commodity prices, (*b*) other costs of medical care, and (*c*) incomes of consumers. "Real" prices of drugs sold by manufacturers, in terms of almost any appropriate measure, have declined. I will not burden you or the record with repetition of these convincing data. Suffice it to say that the record shows that, on a comparative basis, drugs are cheap. They certainly have not contributed to the inflation of prices that has been of so much concern to us all.

II. PROFITS IN THE DRUG INDUSTRY

In the preceding analysis I have shown that strong competition does exist in the drug industry, and that this competition has been responsible for much of the tremendous progress that has been made in recent years in developing new products and therapies, and for making physicians acquainted with these rapid and multitudinous new developments. I am sure that even the severest critic of the drug industry must admit that without this intense competition among the producers of ethical drugs, progress in medicine would have been immeasurably slower and millions of people who at this very moment are enjoying life and health would be suffering from serious diseases or moldering in their graves. To bring this point home to you more forcefully: if there are 400 people in this room, 12 of them would not be alive today if they had not benefitted by the modern drug advances that have occurred since 1937.

But, you may say, granted that competition exists, and in important respects is intense, is it of a kind and degree sufficient to hold profits, and hence prices, within reasonable bounds? Actually, the criticisms of the industry, both direct and implied, that appear in the records of these hearings seems to be based largely upon this question of profits, which it seems some of you consider unduly high. Would it not be better, you have asked, if profits and therefore prices to consumers were lower? To this and associated questions I shall now address myself.

A. Profitability of individual products

Much of the testimony concerning profits, and comment thereon, has related to individual products. Certain costs of bulk materials, packaging charges and selling prices have been used to indicate so-called profits for these particular products.

Nearly all this testimony relating to specific products has dealt, not with profits, but with margins or markups, which are altogether different things.

A profit is a total gross return minus total expenses. Any attempt to arrive at a total or per unit profit on an ethical drug item is foredoomed to failure, because most of the expenses or costs that must be deducted from gross returns, on either a total or per unit basis, are not separable but "joint" costs. There is no satisfactory basis for allocating these joint costs to individual products.

If a rational system of allocating joint costs among all the different products produced and sold by any one manufacturer were available, the picture with respect to apparent margins, markups, or what have been erroneously viewed as individual product profits, would be entirely different from that indicated by certain superficial figures which have been considered by the committee. We would no longer find the ridiculous percentages of alleged profits on individual products to which so much headline attention unfortunately has been given.

Despite these complications involved in even roughly approximating the margins or "profits" realized on individual products of a drug manufacturer, there is no doubt that some of these products are much more profitable than others.

If these joint costs could be allocated, it would be found that the products yielding the highest profit margins are those that are (1) new, and hence not yet "copied," (2) for which no close substitutes are now available, and (3) for which a widespread need exists. As time and competitive research progresses, fully or closely substitutable products will be developed and marketed by other firms, and/or the product will be made wholly or partially obsolete by the discovery of generically different products serving the same purpose better. This happens in practically every case, as evidenced by the extremely high rate of obsolescence. Thereafter, the formerly highly profitable product is either discontinued or becomes one of the many also-rans included in the product mix of any company.

Economists refer to unusual profits made on pioneering products, or as a result of pioneering development of more efficient production or marketing methods, as "profits of innovation." The "profits of innovation" are temporary, persisting only until competitors duplicate the product, develop a better one, or, if the source of the profits is a superior process, adopt the same methods.

Profits on some drug products will appear high to some if price-cost comparisons are restricted to the early stage in their life cycle when the products are unique and the demand is at its peak. By the same token, profits and prices on some drug products would appear low if measured later in their life cycle when substitutes have been developed and demand has fallen. Even limited price-cost and profits comparisons can only be made over the whole life cycle of a product.

At any one time, the product "mix" of any ethical drug manufacturer consists of many different products in all phases of development, marketing and obsolescence. Some of the products in this "mix" are new, the result of years of planning, researching, conferences, laboratory work, pilot plant operation. If they fill a widespread need they may give rise to large sales and better-than-average profits. Without the anticipation and realization of these "profits of innovation" practically none of the continuing research by manufacturers necessary to provide new therapies and to support constantly improving medical practice would or could be undertaken.

Other products, as a result of obsolescence, competition, or limited need, are barely holding their own, or are even being handled at a loss, retained primarily to offer to pharmacists, the medical profession and their patients, a necessary component of some prescriptions.

Obviously, the situation with respect to any one or a few of these products cannot be taken as representative of the whole, even if that situation, profitwise, could be properly pinpointed without the difficulties presented by joint costs and other obstacles that have been described. It would be as silly to judge the profits of the drug industry by high margins for a selected few products as to judge the profits of the automobile industry by profits made on Cadillacs.

If rates of return on individual drug products are compared with overall company profits, it is clear that the product successes singled out for committee attention do not adequately describe the whole range of successes and failures of the individual drug firm. Any attempt to use individual product profits to reflect profits on the many products supplied by the individual drug firm is in error. This procedure misrepresents the average profit component of drug prices. It completely overlooks the fact that the continued existence of a firm

depends upon balancing no-return or lower return, mature products with higher return, unique products.

It is quite evident, therefore, that the only way in which the profits of the drug industry can be measured is by looking at these costs, gross returns, and profits as a whole. The "profit" figures for individual products that have been paraded before this subcommittee by staff members may be a way of raising questions, but they can be misleading to many. They can build up false hopes in the public mind that significant decreases in drug prices can be effected by decreasing these profits. Let us now see if more light can be thrown on this question by examining aggregate or average profits.

B. Profits on invested capital or net worth

Profits stated as so many dollars are meaningless in themselves. Some point of reference is required in order to give such dollar figures significance. In going over the record of the subcommittee's hearings I have noted that a point of reference frequently or even most used has been either net worth or invested capital.

When I see data such as those that have been introduced relating to profits as a percentage of either invested capital or net worth, I wonder whether the effect of some of this testimony will not be to confuse rather than enlighten. Such comparisons may be meaningful to an investment analyst for certain purposes, or to a banker considering credit arrangements for a drug company; but they have no relation at all to the question of how much, if any, drug prices might be reduced by the reduction or elimmination of profits.

Let us take an extreme example outside of manufacturing industry to make the point quite obvious. A hardware store with an investment of $150,000 and a law firm with an investment of $12,000 may each be grossing $600,000 per year, with a profit of $30,000, or 5 percent of sales in each case. Expressed as percentage of investment this would be 20 percent for the hardware store and 250 percent for the law firm. The comparison obviously is meaningless. Some businesses require a large inventory of fixed assets such as land, buildings, and equipment, or raw materials and finished or purchased products, or both. Other businesses have very little money tied up in such physical properties. Any comparisons among them of profits as a percentage of investment are simply figures without meaning except for certain very limited purposes that are not included among those for which they have been used.

Let us look at two more illustrations. Let us take the case of two firms, A and B, not necessarily in the same business, for which we may be trying to judge the "reasonableness" of profits made:

Firm	Investment	Sales	Profits (after taxes)	Percent of sales	Percent of investment
A	$500,000	$2,000,000	$50,000	2.5	10
B	50,000	2,000,000	10,000	.5	20

Now, the untrained person, given only the information that sales of the two firms were equal, but firm B made twice as high a rate of profit on its investment as did firm A, is likely to form the opinion that firm B must have much higher profit margins on sales. Actually, his profits per dollar of sales are only one-half of 1 percent, or one-fifth those of firm A. Even if they were eliminated entirely the buyers of the firm's products would hardly notice the difference.

I do not wish to labor the point; but the subcommittee has so frequently been confronted with such meaningless data, and the latter have apparently been misunderstood even by members of the drug industry, that it will be well to clinch the point with another, more detailed example.

The following hypothetical data (table 1) may be used to represent three different establishments, let us say grocery supermarkets. The principal is applicable to all business.

TABLE 1

	Store A	Store B	Store C
Owns building, $100,000 mortgage, net investment	$80,000		
Owns building, no debt, value		$180,000	
Store C rents building, no investments			
Stock of goods, value	$50,000	$50,000	$50,000
Total capital	$230,000	$230,000	$50,000
Net worth	$130,000	$230,000	$50,000
Annual sales	$900,000	$900,000	$900,000
Interest on mortgage	$5,000		
Cost of building maintenance	$9,000	$9,000	
Annual rent			$18,000
Other annual operating expenses	$837,000	$837,000	$837,000
Total annual expenses	$851,000	$846,000	$855,000
Net profit after taxes	$49,000	$54,000	$45,000
Net profit as percent of sales	5.4	6.0	5.0
Net profit as percent of total capital	21.3	23.5	90.0
Net profit as percent of net worth	37.7	23.5	90.0

Store A owns the $180,000 building in which it is located, on which there is a mortgage for $100,000 requiring $5,000 annual interest. Annual cost of building maintenance is $9,000. Store B owns the building outright, with no mortgage or interest to pay and with the same building maintenance cost. Store C rents the building, paying $18,000 per year but incurring no building maintenance cost. All three of the stores have a stock of goods valued at $50,000, giving a total capital for the three stores of, respectively, $230,000; $230,000; $50,000. But their net worth is, respectively, $130,000; $230,000; $50,000. Annual sales for all three stores are $900,000, and total annual expenses other than building $837,000. Total annual expenses are: Store A, $851,000; Store B, $846,000; Store C, $855,000. This gives a net profit of, respectively: $49,000, $54,000, $45,000, representing, as a percentage of sales: 5.4, 6.0, 5.0. But net profit as a percentage of total capital is, respectively: 21.3, 23.5, 90.0. Profits as a percentage of net worth are: 37.7, 23.5, 90.0.

This example, which is by no means extreme, but representative of situations commonly encountered in business, shows how impossible it is to draw any conclusions regarding profits in relation to prices by referring to profits per dollar of capital or net worth. In the above example, all three stores handled exactly the same merchandise at exactly the same costs other than rent, a minor item, and sold at exactly the same prices; yet the profits per dollar of net worth for store C were nearly four times higher than for store B.

Gentlemen, the primary significance of such data on profits per dollar of capital or of net worth, so far as this subcommittee is concerned, is whether or not they are sufficient to attract or retain enough capital in the industry to give it the means to perform the functions expected of it by the public. It has been largely by the use of retained earnings that the technological growth of the drug industry, its new drugs and new therapies, have been financed. On this point, Messrs. Donald B. Woodward and Banks T. Adams, Jr., have prepared a report to the Pharmaceutical Manufacturers Association which has been made available to you.

Frankly, gentlemen, for the principal purposes of this committee, which are related to drug prices, I would consider all such measures of net profit as a percentage of net worth as being almost meaningless. I believe that any objective economist would agree with what I have said on this subject.

So, gentlemen, may I now address my remarks to profits per dollar of sales.

C. Great variation in profits among individual companies and from year to year

Profit rates among companies in almost any industry vary widely, due to differences in managerial ability, the caliber of personnel built up over the years, and the other circumstances conditioning their operation. In automobiles, for example, some companies went on to make large profits while many others were dropping by the wayside for lack of profits. Over 90 percent of independent retail establishments are said to fail within a few years, whereas others in the same kind of business prosper. Even farmers differ tremendously in the financial results of their operations. Similar disparities exist in the drug industry.

To use the profit figures of any one company or several individual companies, without taking into account these differing circumstances, as indicative of condi-

tions in the industry as a whole can be as misleading as using the profits of a single product as representative of the operations of a single firm. I realize that the temptation to do so is great, since individual companies, like individual products, furnish striking cases in apparent support of points one would like to make. At least, we can all recognize the danger and try to avoid drawing wrong conclusions or creating misleading public impressions by generalizing on the basis of operations not representative of the industry.

Because of these differences among companies, profits per dollar of sales as reported in different analyses of the drug industry differ considerably, according to the companies included. The study by Woodward and Adams, of the 10 companies for which figures are available, shows profit margins for each of the years 1947–58.

Profit margins vary substantially from year to year as well as from firm to firm. The study shows a variation in the profit margins from 9.4 percent in 1953 to 15.7 in 1948. The year 1958 was one of the higher ones, and hence should not be used as representative, even though it is the last year for which data were available to the committee. Profit margins declined from 1957 to 1958 and again from 1958 to 1959, and in all these years were significantly lower than for the years 1947 through 1950 and for the prewar years. The average for the years 1951–55, after the industry had about gotten over the dislocations of the war years, may be about as representative as any for at least the larger companies carrying broad lines of ethical drugs. For the 10 companies included in the PMA study the profit margin was 10.5 percent, for the years 1951–55; for the 10 years 1949–58, which include several of the higher postwar years and the unusual years of 1957 and 1958, the average was 12.2 percent. For 1959, the figure for 8 of the 10 companies so far available was 12.8 percent compared with 13.8 percent for 1957.

The variation in profit margins from firm to firm is also great. Among the 10 companies in the study these margins in 1958, the latest year for which all 10 companies' data are available, ranged from a low of 6.5 percent to 16.8 percent.

These variations clearly indicate the danger of using data for one or a few firms or years to represent the industry.

D. "Reasonableness" of profits per dollar of sales

The words "reasonable" and "fair", as applied to profits, are not economic concepts, and not capable of objective appraisal. But we can seek to explain why profits are what they are, and thereby be in a better position to exercise our necessarily subjective judgment about them.

E. Variations in profits among industries

Profit margins vary widely among different industries, as shown by table 2, taken from a study by Cottle and Whitman.[3] These figures are for the years 1951–55; these most comprehensive materials for this completely objective study do not extend beyond this period, and this is a fairly representative economic period.

There are many reasons for the great variation in profit margins among industries. Most of these may be included in one of four categories: (1) turnover; (2) degree of risk; (3) circumstances such as growth rate and position on the industry cycle, if any; and (4) external conditions such as the business cycle.

Of these, one of the most important is turnover of both inventory and capital. This may sound surprising to the layman, but not to any businessman or economist who has observed the importance of this factor. Any business with a high turnover may make a very small profit per unit or per dollar of sales and still accumulate a respectable total by income tax time. The same applies to different lines of products.

Cottle and Whitman (p. 31) have given rates of turnover of total capital for the industries included in table 2. If rates of profit given in this table are plotted against the corresponding turnover rates for the respective industries, a very substantial degree of correlation is observed. The relationship also appears to be definitely curvilinear; i.e., the lower the turnover rate the greater the proportionate effect upon profit margins of a change in such rate.

[3] Cottle and Whitman, "Corporate Earning Power and Market Valuation," Duke University Press, 1959, p. 30.

When the profit margins shown in table 2 are adjusted by readings from the curvilinear regression depicting the above relationship (see the second column of table 2), they appear entirely different. The apparently low profit margins now closely approach the average, and the higher ones do likewise. The previously apparent discrepancies among industries disappear to a substantial degree. The factor of turnover, in fact as well as in theory, has partly explained why some industries have relatively high profit margins and some have relatively low ones.[2]

TABLE B.—*Average net profit margin,[1] 1951–55*

	Unadjusted [2]	Adjusted [3]
Copper	15.1	9.6
Oil	12.0	8.2
Ethical drugs	10.1	7.5
Chemicals	9.5	6.1
Building materials	9.2	5.0
Paper and allied products	8.8	6.3
Proprietary drugs	7.8	3.8
Corn products	7.4	5.7
Automobiles	6.6	8.4
Steel	6.5	4.4
General industrial machinery	6.2	5.5
Glass containers	5.6	5.2
Electrical supplies and equipment	5.4	5.7
Toilet preparations and soap	5.3	5.4
Agricultural machinery	5.2	2.9
Automobile parts and accessories	4.7	5.9
Rubber	4.6	4.7
Mail-order houses	4.4	4.8
Cigarettes	4.4	3.1
Distilling	4.3	2.6
Metal containers	4.3	3.5
Limited-price variety	4.0	3.7
Textile fabrics	3.8	2.5
Radio and television	3.6	5.3
Packaged foods	3.4	4.8
Apparel and accessory chains	3.3	6.4
Aircraft	3.0	7.8
Department stores	2.8	3.5
Dairy products	2.7	4.5
Grain mill products	1.9	4.8
Grocery chainstores	1.0	6.5
Meatpacking	.6	5.5

[1] Net profits after taxes as percent of sales.
[2] Cottle & Whitman, "Corporate Earning Power and Market Valuation, 1935–55," Duke University Press, 1959, p. 30.
[3] Adjusted for values of curvilinear regression of profit margins on rates of total capital turnover by adding algebraically, to the average for all industries, the deviations from the corresponding regression values.

Contrary to what might be expected without more thorough examination of the industry, ethical drug firms have a relatively slow annual turnover of capital (only 1.30) compared with the lowest of the industries included, copper (.72) and the highest, grocery chainstores (8.54). In other words, for the ethical drug firms included in the PMA study, annual sales were only 30 percent greater than capital, or it required $1 of capital to support each $1.30 of sales. This serves to explain in large measure the relative position of the ethical drug industry in regard to profit margins.

If satisfactory quantitative measures of the three other groups of factors affecting margins were available, and time permitted, they could be used in a multiple correlation analysis to explain the differences in profit margins among industries not accounted for by capital turnover. If this procedure were carried to a completely logical and statistically successful conclusion, all of the adjusted figures shown in the second column of table 2 would be the same, namely, the average figure (5.5).

[2] Since turnover may be used to convert profit margins to profits per dollar of capital or net worth, and we have discarded the latter as meaningless in relation to prices, there may appear to be a large element of circular reasoning and inconsistency in using turnover to explain variations among industries in profits per dollar of sales. Actually, all that this means is that neither measure has any economic significance in relation to the question of how much drug prices could be reduced by reducing or eliminating profits, as will be expalined later. Variations in profit margins among industries have no more economic significance in relation to the committee's deliberations than profits per dollar of net worth.

F. Profits in relation to prices

It has been shown that profits as a percentage of net worth cannot be used to draw significant economic conclusions in relation to possible reductions in prices. It has been shown, also, that profits per dollar of sales (profit margins), although higher for the drug industry than for some other industries, are largely explainable in terms of factors common to all industries. Neither of these measures of profits, on a relative basis, has any significant economic relation to the question of how much drug prices might be reduced by reduction or elimination of profits. However, some light may be thrown on this question by consideration of absolute, as opposed to relative, profit margins.

According to data obtained by your committee from 20 firms for the year 1958, the average profit was 13.1 percent of sales. It has been shown that 1958 was an abnormally high profit year, as was 1957. For the period 1951–55, the Cottle & Whitman figure was 10.1 percent and the Woodward-Adams figure for the larger group of companies was 10.5 percent. For the 10 year period 1949–58, the profit margin was 12.2 percent for the latter group. But this is on manufacturers' sales. Significant costs are incurred after the manufacturer sells the drug to the trade, reflecting the high standards that the consumer demands of the entire medical services industry. Drugs cannot be handled in the trade in the same manner as nails or sugar, and trade markups necessarily are higher than for such staple commodities. Although I have no specific data on this point, I believe it may be said with confidence that the price paid by consumers for prescription drugs, after the wholesaler's and retailer's markups have been added, is at least twice that received by the manufacturer. So it is evident that manufacturers' average profit per retail dollar paid for drugs is roughly 6 percent.

G. Elimination or reduction of profits no panacea

I believe that even the most ardent critics of the drug manufacturing industry would not have it operate at a no-profit level. Let us presume that they would not object to manufacturers' profits of, say, 3 or 4 percent per dollar of retail sales. Whatever this subjectively determined figure might be, the difference between it and 6 percent would not represent much in terms of retail drug prices, at the most a few cents on a dollar's worth of prescription drugs.

In fact, if the entire profit of drug manufacturers were wiped out completely, buyers of consumer drugs on the average would hardly notice the difference in prices, which could easily be lost in the shuffle. Small changes in wholesale prices frequently are not reflected in retail prices. No, the concern that has been felt over drug prices has not been on the order of a few pennies per dollar, but of fancied profits running to many hundreds or thousands of percents, that do not exist in reality because the false measures of costs that have been used to adduce such figures have not taken properly into account all costs, position on the life cycle of the drug, and other conditions that have been dealt with in the foregoing analysis.

A company-by-company approach to the drug industry, and the singling out of the most profitable items in each company's line, coupled with inadequate measures of costs, can produce a totally erroneous impression of the across-the-board possibilities for price reductions through profit elimination. Only a very small reduction in the level of drug prices, and an even smaller percentage reduction in the total cost of a cure, would result if all profits of all the drug companies were wiped out.

III. THE PUBLIC'S REAL INTEREST IN DRUG PROFITS AND PRICES

The price that society has paid in the form of drug industry profits is, in the aggregate, very low. The consumers' alternatives of longer hospitalization, more time lost from work, and more medical services would have been far more costly than the aggregate profits of the drug industry.

Even if all drug manufacturers' profits were wiped out, the problem presented by the low-income consumer and the chronically ill would remain, and costs to the ordinary in-and-out user of prescription drugs would not be reduced enough to pay for his daily newspaper.

In fact, the temporarily high "profits of innovation" accruing from the production and sale of a few drugs during the early phases of the products' life cycle, by stimulating research and development by the originating firm and its competitors, in the long run undoubtedly serve to minimize the total costs of medical care to the consumer and society. These profits induce private capital

to devote research and manufacturing resources to the risky undertaking of pioneering new drugs. Prospective gains must be large enough to compensate for unusual risks.

In the midst of a technological revolution society properly demands an outpouring of research and education resources to rapidly bring benefits to consumers. In order to obtain the speed, daring and flexibility of a private enterprise solution of this social problem, society must pay rewards which in the case of some unusually successful innovators may appear large. Even when research is successful, the financial advantages flowing from it in the drug industry are usually short lived. If profits on such newly discovered, short-lived products were greatly reduced or eliminated, then investment in research and development to produce similarly unique products would be discouraged. In an enterprise economy the level of profits determines incentives. There is no way to tamper with profits without affecting incentives. In the drug field, these incentives are of the utmost importance in promoting advancement in medical science and practice, the discovery of new therapies and the improvement of the health and well-being of all of us.

The research which has led to the development of so many tremendously useful drugs since World War II already is behind us. The much more difficult research, the research where risks of failure are greatest, lies ahead. Cancer and other important diseases give rise to prodigious research problems. One drug manufacturer already has expended over $7 million in the search for a chemical that might be useful in the treatment of cancer, with no marketable product resulting. If the manufacturers' increasing chances of loss are coupled with new penalties for success, it is hard to see how the consumer can gain. To condemn an industry or a firm for its ability to maintain profits through successful new product development will not only discourage profits, but much more importantly the unique efforts that have produced these profits.

In my humble and very sincere opinion as an economist, gentlemen, the committee's primary concern should be with the incentive function of profits, since consumer welfare stands to be benefited most by research and product development yet to be done. Society's alternatives to sickness, mortality, and inefficiency are priceless compared with the profits of the drug industry which can contribute so much to reducing them in the future.

Senator KEFAUVER. Thank you, gentlemen.

(Whereupon, at 1:55 a.m., the committee recessed, to reconvene at 9:30 a.m., Wednesday, February 24, 1960.)

ADMINISTERED PRICES

WEDNESDAY, FEBRUARY 24, 1960

U.S. SENATE,
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to recess, at 9:40 a.m., in the caucus room, Old Senate Office Building, Senator Estes Kefauver, presiding.

Present: Senators Kefauver (chairman) and Hruska.

Also present: Paul Rand Dixon, counsel and staff director; Horace L. Flurry, counsel; Peter N. Chumbris, counsel for minority; Nicholas N. Kittrie, counsel for minority; Lucile B. Wendt, attorney; Bushrod Howard, attorney; Dr. John M. Blair, chief economist; Dr. E. Wayles Browne, Jr., economist; Dr. Irene Till, economist; Herschel Clesner, special consultant; Paul S. Green, editorial director; and Gladys E. Montier, clerk.

Senator KEFAUVER. The committee will come to order.

Dr. Smith has supplied the list of the members of the Pharmaceutical Manufacturers Association. That will be made exhibit 230 in the record.

(Exhibit 230 may be found on p. 10952.)

Senator KEFAUVER. Last night in colloquy particularly with Dr. Thomsen, the table from Stanford Research Institute of September was discussed at length but I do not believe it was made a part of the record. That will be 231.

(Exhibit 231 may be found on p. 10954.)

Senator KEFAUVER. I believe that Dr. Blair had two pages on an earlier exhibit and only one was put in by mistake.

Mr. DIXON. The exhibit is 223.

Senator KEFAUVER. That will be made a part of exhibit 223 then.

(The complete exhibit 223 may be found on p. 10943.)

Senator KEFAUVER. We want to move on as quickly as we can because, as matters now stand, unless there is some change we will only have a little less than 1 hour to go this morning.

I understand that Dr. Wayles Browne and Dr. Smith have had some discussion about research expenditures. Dr. Browne's calculations were based on 22 companies. The subcommittee distributed a questionnaire for which research and development costs were requested and then other research costs and those costs were combined, and then calculated against the total sales of the company. Based on that, the subcommittee's figure on research is 6.4 percent and Dr. Smith's is 9.5 percent. I believe Dr. Smith was going to get the supported data for us. Dr. Browne, can you tell us what the situation is in that connection?

Dr. BROWNE. Yes, I understand from Dr. Bambach of the PMA that the figures he used, he collected, had to be returned to the manufacturers themselves, so that it is not now possible to produce his figures for a comparison with ours.

With a fairly wide definition of research and greater coverage in the industry I think there is no doubt that $170 million on research under your definition would be quite possible to collect.

However, Dr. Bambach seemed to have about a billion eight in sales, which I believe he tells me were partly estimated.

If you divide 170 million by 38, you get the 9.5 percent which Dr. Smith used. However, the figures we have on a somewhat smaller sample give us——

Senator KEFAUVER. Of 22 companies.

Dr. BROWNE. Of 22 companies give us two billion three in sales of drugs alone, and I feel sure that complete coverage of this industry would bring it up to two billion four or two billion five. Even with $170 million spent on research divided by say 2.4 or 2.5, the proportion spent on research would still be less than 7 percent of sales, so that while the 170 million may be a reasonable figure, I do not see that we could accept the 9.5 percent of sales as reasonable, particularly since it is not possible to produce your figures to compare with the ones we have.

Senator HRUSKA. Doctor, are the periods of your information of the sales of 2.3 the same period that was used by the other survey which showed sales of 1.8?

Dr. BROWNE. That is my understanding, sir, we used the calendar year of 1958 on our questionnaire, and all but two companies gave us calendar year figures, and those two that used figures for the fiscal year slightly off only represented less than 10 percent of total, so the time period is almost identical.

Senator HRUSKA. Dr. Smith, was the calendar year 1958 used in your questionnaire?

STATEMENT OF DR. AUSTIN SMITH—Resumed

Dr. SMITH. I was conferring with Dr. Bambach, Senator, and if I could have your permission I think he could give an explanation that is clearer than the one I could because this survey was undertaken before I joined the PMA. There is one thing that bothers me and that is the total sales about which I certainly have some confusion and I can't reconcile Dr. Browne's figures and ours.

Senator KEFAUVER. Yes, if he will be very brief.

Dr. BAMBACH. Thank you, Mr. Chairman, and gentlemen. The figure of 170 million for total research and development expenditures of the industry was arrived at by using a definition that has been supplied to Dr. Browne and it is a definition of research and development.

This definition was worked out by the National Institutes of Health in cooperation with us and appears to be quite satisfactory to us.

Senator KEFAUVER. Let's put the definition in the record.

Dr. BAMBACH. And of course it is satisfactory to them.

Senator KEFAUVER. This will be exhibit 232.

(Exhibit 232 may be found on p. 10957.)

Senator KEFAUVER. Go ahead, sir.

Dr. BAMBACH. I explained to Dr. Browne that in attempting to estimate the total dollar sales of the industry, particularly those of medicinals, it is quite difficult to do that.

Our figures, the figures which is reported to us, are those which each company will give us each year for the purpose of assessing the dues. The dues schedule was referred to yesterday, and it is the amount which each company pays in accordance with the total annual business in the pharmaceutical field.

Now that in some companies may include some veterinary business, it may include some business in medicated feeds or perhaps it does not. We accept the figure which the company gives us on its total annual sales for the purpose of assessing, of invoicing, each company for dues to the association in accordance with the schedule I mentioned.

Senator KEFAUVER. For dues-paying purposes they don't report the same figures as they would in answer to our questionnaire of their total sales?

Dr. BAMBACH. That is correct.

Senator KEFAUVER. You have $1,800 million, whereas in their reports to us, 22 companies had $2,300 million.

Dr. BAMBACH. Yes, I would not know whether your figures would include export, would include medicated feeds, would include veterinary items, might include some medicinal chemicals.

Dr. BROWNE. I am sure they would, Doctor, but it seems to me that the research expenditures certainly also apply to items that are exported. There is no difference between an export item and a domestic item so far as research is concerned. The medicated feeds certainly are affected by research in the vitamins and the antibiotics. It seems that your exclusions while perhaps quite reasonable for dues-paying purposes are not at all reasonable for comparing total sales with total research expenditures to get the percentage figure.

Dr. BAMBACH. That is probably the case. I think that some research on medicated feeds would not necessarily be included in the research figures which we have.

Senator KEFAUVER. In other words, you don't charge dues on drugs that are exported?

Dr. BAMBACH. In some cases, yes, we expect the companies to report to us, including in their estimates the amount of export business generally. That they generally do.

Senator HRUSKA. What about the veterinarian supplies and the medicated——

Dr. BAMBACH. The companies are permitted to exclude items not in the medicinal line of products which are used by the medical, by the physician and allied professions.

Senator KEFAUVER. Say that again?

Dr. BAMBACH. Companies are permitted to exclude items, sale of items, which are not included in the group of medicinals used by physicians and the allied professions.

Dr. BROWNE. What you have then is a broad definition of research and a very restricted definition of sales.

Dr. BAMBACH. We have never purported to have an accurate sales figure.

We feel that our research figure is solid.

Senator KEFAUVER. I think we understand. You don't purport to have an accurate sales figure.

Dr. BAMBACH. Not from our own association figures; no, sir.

Senator KEFAUVER. I would take it that these 22 companies reported to us their sales of ethical drugs. If that totals up to $2,400 million you wouldn't dispute that figure?

Dr. BAMBACH. I don't know.

Senator KEFAUVER. All right. Any questions of Dr. Bambach before we move on? That is all. Thank you.

What is next, Mr. Dixon?

Mr. DIXON. Mr. Chairman, on page 15 of Dr. Smith's statement he says that on the basis of the record this subcommittee will have to conclude that the ethical drug manufacturing industry is one of the most competitive ever examined. We have prepared a table from the information that was received from the 22 drug companies that account substantially for the bulk of the sales of the total ethical drug field. I will ask Dr. Blair to explain this table which is on the easel.

Senator KEFAUVER. Let's make this table exhibit 233.

(Exhibit 233 follows:)

Concentration of production, 1958, hormones, diabetic drugs, tranquilizers, vitamins and antibiotics (revised)

	Hormones								Diabetic drugs			Tranquilizers						Sulfas								
	Hydrocortisone	Cortisone	Methyltestosterone	Prednisolone	Prednisone	Progesterone	Triamcinolone	Dexamethasone	6-methyl prednisolone	Insulin	Diabinese	Orinase	Reserpine	Hydroxyzine	Chlorpromazine	Prochlorperazine	Perphenazine	Promazine	Meprobamate	Sulfisoxazole	Sulfadiazine	Sulfamethoxypyridazine	Sulfapyridine	Sulfapyridine, sodium	Succinylsulfathiazole	Phthalylsulfathiazole	Sulfathiazole	Madribon
Abbott	----	----	----	----	----	----	17	----	----	----	----	----	----	----	----	----	----	----	----	----	100	100	100	100	----	----	73	----
Am Cyan	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	100	----	----	----	----	----	----	----	----	----	----
Am Home	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----
Bristol-Myers	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	100	----	----	----	----	----	----	----	----	----
Carter	----	----	----	----	----	----	----	----	----	----	----	----	56	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----
Ciba	----	----	100	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	100	----	----	----	----	----	----	----	100
Hoffmann LaRoche	----	----	----	----	----	----	----	----	----	77	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	27	----
Lilly	33	30	----	33	9	----	83	74	----	4	----	----	----	----	----	----	----	----	----	----	----	----	----	100	100	----	----	----
Merck	----	----	----	----	----	----	----	----	----	19	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----
Olin-Mathieson	----	----	----	----	----	----	----	----	----	----	----	----	----	100	----	----	----	----	----	----	----	----	----	----	----	----	----	----
Parke, Davis	----	----	----	22	89	----	----	26	----	----	100	----	----	----	----	----	100	----	----	----	----	----	----	----	----	----	----	----
Pfizer	28	----	----	----	----	100	----	----	100	----	----	73	----	----	100	100	----	----	----	----	----	----	----	----	----	----	----	----
Schering	----	33	----	----	----	----	----	----	----	----	----	----	56	100	----	----	----	----	----	----	----	----	----	----	----	----	----	----
Smith Kline & French	39	28	----	45	2	----	----	----	----	3	1	2	2	1	1	1	1	1	100	1	1	1	1	1	1	1	2	1
Upjohn	3	3	1	3	1	----	2	2	1	3	1	2	2	1	1	1	1	1	100	1	1	1	1	1	1	1	2	1
Producers	100	100	100	100	100	100	100	100	100	100	100	73	56	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Percentage total	100	100	100	100	100	100	100	100	100	100	100	73	56	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

[1] Carter controlled all production by license under patent although producing none itself.

Source: Reports by companies to the subcommittee.

	Vitamins									Antibiotics									Penicillin				
	A	B_1	B_2	B_6	B_{12}	E	Biotin	Folic acid	Ascorbic acid	Chloramphenicol	Aureomycin	Dihydrostreptomycin	Erythromycin	Nystatin	Oleandomycin	Terramycin	Streptomycin	Tetracycline	Benzathine G	Benzathine V	Potassium G	Potassium V	Procaine G
Abbott								3					35								2	17	1
Am Cyan				6				65			100	5					6	33					
Am Home																			99	100	23		16
Bristol-Myers																		36			9		1
Carter																							
Ciba																							
Hoffmann LaRoche	28	44	59	46			100		35														
Lilly												10	65				2				6	83	22
Merck	2	56	30	48	100	100			27			44					16				22		6
Olin-Mathieson												25		100			46				28		28
Parke, Davis										100													
Pfizer	36	(1)	(1)						38			16			100	100	30	31	1		10		26
Schering																							
Smith Kline & French																							
Upjohn								32															
Producers	5	3	4	3	1	1	1	3	3	1	1	5	2	1	1	1	5	3	2	1	7	2	7
Percentage total	66	100	90	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

[1] Less than ½ percent.

Source: Reports by companies to the subcommittee.

Senator KEFAUVER. Very well, Dr. Blair.

Dr. BLAIR. Mr. Chairman, this table as presented here in the blown-up form on the easels is supposed to be one continuous table; the eye is supposed to move from the far left corner of the chart on the easel on the left over to the far right corner of the chart on the easel on the right. The same impression can be gained from the mimeographed table by regarding page 2——

Mr. DIXON. Dr. Blair, I think they are reversed. If you reverse your charts, your explanation from left to right would be more accurate.

Dr. BLAIR. I would really prefer to reverse the charts rather than the discussion.

Senator KEFAUVER. There are two tables. Shall we make them separate exhibits?

Dr. BLAIR. No, sir. Visually the same effect can be gained by regarding page 2 of the mimeographed sheet as an extension of page 1. What this chart represents, Mr. Chairman, is concentration ratios for the major drug products which are being studied by this subcommittee. As in the case of all concentration ratios, there are two essential types of data which must be obtained, the numerator and the denominator.

The numerator is derived from the figures reported to this subcommittee by the companies in response to our questionnaire.

The denominator in most cases is the total production in the United States, which is taken from the published reports of the U.S. Tariff Commission. However, in some cases where the Tariff Commission does not present adequate detailed data, the total universe figures have been derived by the subcommittee from other sources, principally the reports to the subcommittee itself.

Mr. Chairman, to see how the table operates let us refer for example to Merck, which will be seen about halfway down the first page on the mimeograph table.

There it will be seen that Merck produces 33 percent of the U.S. output of hydrocortisone, 39 percent of cortisone, 33 percent of prednisolone, 9 percent of prednisone, 74 percent of dexamethasone, and so on across for the other items on the table. It will be noted thus that Merck produces 4 percent of insulin, 100 percent of two of the sulfas, and 27 percent of a third, and turning to the second page of the mimeographed form it will be seen that Merck produces 2 percent of vitamin A, 56 percent of vitamin B_1, 30 percent of vitamin B_2, 48 percent of vitamin B_6, 100 percent of vitamin B_{12}, 100 percent of vitamin E, and 27 percent of ascorbic acid. It will also be noted under antibiotics that Merck produces 44 percent of dihydrostreptomycin and 16 percent of streptomycin. It also produces 22 percent of potassium G penicillin and 6 percent of procaine G penicillin.

At the bottom of the table it will be noted that there are in the left column the words "percentage total". That represents of course the percentage of the U.S. output of the product accounted for by the companies shown above. Then immediately above that is the item "producers." That relates to the number of companies among these large firms which in the questionnaire reported to us production of that particular product.

Thus it will be seen that hydrocortisone is produced by three companies according to the reports to us, and our examination of all existing sources indicates that these are the only three companies that produce this product.

I am talking about production of the basic product itself and not the number of companies involved in the process of compounding and tableting the basic product into pills.

Now it will be noted that in the first category, hormones, there are nine products. In three of these products, namely methyltestosterone, progesterone, and 6-methylprednisolone, 100 percent of the U.S. output is accounted for by one company.

In two others, triamcinolone and dexamethasone, 100 percent of U.S. output is accounted for by two companies. In 4 other products, 100 percent of U.S. output is accounted for by three companies.

The summary figures for the other product categories are as follows:

Diabetic drugs: in the case of one of the products, Diabinese, 100 percent is accounted for by one company, the sole producer in the United States being Pfizer. One hundred percent of the U.S. production is accounted for by two companies in the case of one other diabetic drug, Orinase, which is produced by one of the companies shown in this table, namely Upjohn, and the remainder is produced in this country by a manufacturing plant owned by Hoechst of Germany.

The third item under diabetic drugs is insulin of which 73 percent of the output is accounted for by three companies. Tranquilizers it will be noted that out of the tranquilizers shown——

Senator KEFAUVER. Seventy-three percent seems to be Orinase.

Dr. BLAIR. That is correct, I misread the figures. I will correct myself; 73 percent of the total output of Orinase is accounted for by Upjohn. As I said before, the remainder is accounted for by a company not shown in this list, a company not within the 20 largest producers in this country, namely the Hoechst subsidiary in the United States. Now in the case of insulin, 100 percent of the output is accounted for by 3 companies, the most important of which is Lilly, which produces 77 percent of the U.S. output.

Under tranquilizers it will be noted that there are seven tranquilizers for which data were obtained which account for the great bulk of tranquilizer sales. In all but one of these products, 100 percent of the output was accounted for by just one company. The exception is reserpine, in which the largest company accounts for 56 percent.

In the case of the sulfas, the next category, there are nine products. Again it will be noted that in eight of the sulfas 100 percent of the output is accounted for by one company, and in the other product, which is sulfathiazole, 73 percent is made by American Cyanamid products and 27 percent by Merck.

Moving on to vitamins we find that of the nine products there are three in which 100 percent of the output is accounted for by one company, vitamins B_{12}, E, and biotin. In two cases, the company making the 100 percent is Merck.

Senator KEFAUVER. I don't know whether you want to go into the details on vitamins there.

Dr. BLAIR. Yes, there are four other vitamins in which 100 percent of the output is accounted for by three companies, vitamin B_1, vitamin B_6, folic acid, ascorbic acid.

Senator HRUSKA. Where is that found on the chart, Doctor?

Dr. BLAIR. The second entry over is vitamin B_1. There you will note the figure 3 and below it 100 percent, meaning the three companies account for 100 percent of its total output. It will be noted that 56 percent is produced by Merck and 44 percent by Hoffman La Roche, with Pfizer accounting for a trace.

In antibiotics other than penicillin, it will be noted that there are nine products. Of these nine, 100 percent of the output in five products is attributed to one company. In one product 100 percent of the output is accounted for by two companies, in another by three and in two others by five.

Finally there are five penicillin products. Output of 100 percent is accounted for by one company in the case of one product, which is Benzathine V. In two products 100 percent is made by two companies, and in the other two by seven. These latter are what are known as the old forms of penicillin.

Mr. Chairman, making an across-the-board summary, there are a total of 51 products shown on this table. In 27 of these 51 products, 100 percent of the output is accounted for by 1 company. In 8 more products 100 percent is accounted for by 2 companies, and in 10 more 100 percent by 3.

Mr. Chairman, according to our best information, the products on this table represent at least two-thirds of the 1958 value of ethical drugs.

As I indicated at the outset, these product categories represent the areas which the subcommittee has selected for special attention because of their newness and because of their great importance to medical science. I might also point out, that in the case of one of the tranquilizers, meprobamate, the table shows that 100 percent of the output is accounted for by one company; namely, Carter. You will note a footnote to that entry indicating that, as was brought out in our preceding tranquilizer hearings, Carter itself does not make meprobamate, but has the product made for it by five other companies, none of which sells meprobamate.

Senator KEFAUVER. Except in gross.

Dr. BLAIR. Except in bulk form of course to Carter.

Senator KEFAUVER. It would seem from these tables—and we will ask Dr. Smith to comment—that there are very few of these larger drug companies that have a complete line of drugs. They seem to specialize in particular items, one like Merck making steroid hormones, but it doesn't make tranquilizers, some making tranquilizers and not making anything else, some making sulfas and a few other products, some making vitamins and not many other products, some making antibiotics and not many other products, although there are some companies here that seem to have fuller lines.

Merck seems to have a number of products and Pfizer seems to have a number of products. The chart shows the products they make.

Dr. BLAIR. That is correct. The companies differ very considerably in the extent to which they are what might be referred to as "full-line" firms, insofar as production is concerned.

The companies which make many products are principally American Cyanamid, Merck, and Pfizer, and at the opposite extreme are companies such as Smith Kline & French, which makes only 2 of the 51 products included in this table, or Parke, Davis which makes only one.

In addition, there are——

Senator KEFAUVER. I think we ought to make this clear. I understand from the testimony we have had here that whereas many of these companies do not make all these products, practically all of them buy the products from somebody else and when they go to sell them they do have a fairly full line.

Dr. BLAIR. Finally Mr. Chairman, I should point out a fact which is not indicated by the table.

This information was sought from the 22 largest drug manufacturers. Six of these companies reported no production of any of these products whatever.

Senator KEFAUVER. All right. Do you wish to make any comment, Dr. Smith?

Dr. SMITH. Yes, Mr. Chairman, I am not surprised that figures like this would be developed. I think it only shows that companies are producing what is needed. Furthermore, as I looked over this list, and I admit I looked over it hurriedly because I was trying to listen to what Dr. Blair was telling us, I think in most instances the doctors are not confined to the use of these drugs.

Perhaps what is represented here is the typical American patent system.

Now in the beginning, I suggested that perhaps I could be more useful to the subcommittee if I could discuss the industry as a whole.

I am not qualified to speak about a product or a firm. Frankly I don't know such business practices. So with that thought in mind, may I say that some time ago in an attempt to satisfy my own curiosity about concentration in the drug industry, I asked an organization to prepare a study on this for me. On the basis of the information supplied subsequently it was decided to ask the National Industrial Conference Board for a study, and this conference board has submitted a report to me. It is based on data from the Census of Manufactures, and according to the footnote in the report, this is based on the 1957 Antitrust Subcommittee report on concentration in American industry, the report of the Subcommittee on Antitrust and Monopoly to the Committee on the Judiciary, U.S. Senate, 85th Congress, in July of 1958.

To save your time and not go through this entire report I would like to read just three or four sentences. One has to do with a summary of facts.

It mentions pharmaceutical preparations, and this tends to support the earlier report which aroused my curiosity. This sentence reads:

Concentration in—

Senator KEFAUVER. Are you reading from this subcommittee's report on concentration?

Dr. SMITH. No, this is additional information provided from which is reference material, the same way that Dr. Blair has been using reference material.

Senator KEFAUVER. Very well.

Dr. SMITH (reading):

Summary of facts: Study of standards for these companies for the 1947–56 period gives little cause for concluding on the basis of the ratio alone that concentration in drugs and medicine has become a major economic problem.

It goes on to say a little further in the report submitted to me:

Concentration in pharmaceutical preparations in terms of the share of industry shipments accounted for by the first 4 companies declined from 28 percent to 25 percent between 1947 and 1954, and for the first 8 companies it remained constant at 44 percent and for the first 20 companies it moved over a slight range from 64 to 68 percent. It is concluded that since primary and secondary product problems are not serious for this industry, that these contration ratios have a relatively high degree of reliability.

Then another footnote further in this report which I think bears on the statement and I am sure would be of assistance to this subcommittee, is this:

With the concentration ratio of 25 percent for the first four companies, the pharmaceutical preparations industry ranked closest to the lowest quartile of all industries in size of concentration ratio. Indeed 300 of the 447 manufacturing industries had higher ratios and 80 others had the same concentration ratio for the first 4 companies in that year.

Mr. Chairman, since I feel I am at liberty only to speak to the industry as a whole, I, therefore, can use only these portions of the report. I cannot speak on the individual company or product.

Dr. BLAIR. Mr. Chairman, I would like to comment briefly upon Dr. Smith's observation. There are two sources among the various Government agencies of what I referred to as universe totals or denominators of concentration ratios for drugs. One is the U.S. Tariff Commission; the other is the Census of Manufactures. The Census of Manufactures, as we all know, obtains total shipments figures for all U.S. industries, and because of its necessary preoccupation with obtaining valid statistics for the entire economy, the product categories used in the Census of Manufactures are frequently too broad for any meaningful purpose. It is for that reason that the Tariff Commission has, for years, been obtaining more detailed product data for the drug industry.

I believe that the Tariff Commission data are much more widely utilized than are the Census of Manufactures figures for the drug industry.

We have here employed the product categories developed over a long period of years by the U.S. Tariff Commission. The Tariff Commission tends to be somewhat of a specialist in this area of chemicals, drugs and related products. Obviously, the broader the categories, generally speaking, the lower the concentration ratios. That, I believe, is the principal factor which accounts for the lower level of concentration revealed for this particular industry by the Census data than by the U.S. Tariff Commission figures.

Mr. CHUMBRIS. Mr. Chairman, may I interject for just one moment?

Senator KEFAUVER. Mr. Chumbris?

Mr. CHUMBRIS. I am referring to volume 3 of the transcript when Mr. Carter was testifying on page 468. He introduced a chart which shows, as he testified, the great competitiveness in the drug industry. He pointed out that he had 100 percent of Cortone in 1950.

Senator KEFAUVER. Cortisone?

Mr. CHUMBRIS. He has it as Cortone. That is his trade name. Then, in 1952, two other products came into the picture and he dropped down to 78 percent. By 1956, because of competition and drive for new and better products, he was down to 3 percent of the field, and meticortone came in with 53 percent and sterin with 8 percent and 15 percent for others.

Then in 1959 he was completely out of the market with cortone, and you had 7 different competitors in the field of corticosteroids. So this subject has been delved into by the different witnesses when they appeared, and I can understand Dr. Smith says that he doesn't like to talk about any particular company, but I think that this exhibit is a perfect indication of the competitiveness in drugs, and you may have 100 percent of the market because you save a patent on a new drug, but a couple of years later you are completely off the market and someone else is taking the market away from you.

Dr. SMITH. Mr. Chairman, I am a little confused because Dr. Blair said that the Federal Tariff Commission—I think he implied, were more widely utilized, but according to my report the Census of Manufacturers formed the basis for the 1957 report of concentration in American industry.

Dr. BLAIR. That is correct, sir. When one derives concentration ratios for every manufacturing industry, the only source is the U.S. Census of Manufactures. However in the field of drugs, partly because of the known inadequacies of the Census definitions, the Tariff Commission has devised and publishes each year a more meaningful set of product categories.

Mr. Chairman, in answer to Mr. Chumbris, I want to point out that while it is true, as we have certainly developed and tried to stress in both the tranquilizer and the corticosteroid hearings, that there is a certain degree of product competition between one product and another, nonetheless there is also a very high degree of company specialization, and the same companies appear among the different products within a broad product category. For example, in hormones among the 9 different products shown there are only 7 of the 20 largest companies represented. In diabetic drugs there are only five companies, in tranquilizers only six. In sulfas, there are only three. In vitamins there are only six; in antibiotics, other than penicillin, eight; and, of course, in penicillin, seven.

Now, whether a given product is competitive with another product or not, such as dexamethasone being held by Merck to be superior to prednisone, it is still a fact that the production of dexamethasone is concentrated entirely in the hands of Merck and Schering, and 89 percent of the output of prednisone is made by Schering.

This same pattern obtains throughout all of these product categories, with the exception of the older forms of penicillin.

Dr. SMITH. Mr. Chairman, it seems to me this is not unusual. After all, there are many firms that specialize, and I think serve the patient much better by the nature of their specialization. If I could, without naming the firm, just cite a personal experience of years ago, I remember a firm that used to have more than 600 products in its line and it elected to reduce those and reduce them and reduce them until it had ruled out those that it felt did not serve a particularly

useful purpose. It got down to about 12 or 14. I think this firm now makes something like 30-odd. At least, that was a count that I had made several years ago, and yet this firm is doing better than ever before in its attempt to serve the public. So I think that very often a firm by specializing in an area serves better the patient.

But, most importantly, Mr. Chairman, these things that are mentioned here with the possible exception of a few—since I haven't had time to study this chart I have to make that reservation—do not restrict the physician in his choice of treatment for patients. He has a choice.

Senator KEFAUVER. I want to say, Dr. Smith, that I have been chairman of this committee for some time. While there are many companies in the ethical drug field, of the principal drugs which constitute a large part of the ethical drug field as shown here, either by patent arrangement or by licensing or by some other arrangement, there is a remarkable degree of concentration of manufacturing of these specific drugs. It is by far the highest concentration that I have seen in any industry.

Mr. Chumbris referred to some of the corticosteroids. A table has been presented earlier in these hearings relating to prednisone and prednisolone. We found that even in those cases where the three companies are the total manufacturers of the bulk finished product, some of them do buy from Merck, although there was an effort to have a licensing agreement prohibiting the sale—which has been brought out here—of anything but finished form. But Pfizer first broke the ice and then Merck followed after this agreement had been in effect for some time. And a number of little companies are buying the finished product from Merck or from Pfizer in the bulk product. We still find that even though Merck, Pfizer, and Upjohn have 33, 22, and 45 percent of the manufacture of the finished product, some of it does get out to the smaller manufacturers; but, of course, Schering has the patent for prednisone, and the small manufacturers apparently disappear for that product.

But we find with prednisolone, even in spite of the fact that some of it is being sold in bulk product to the small companies, that these three large companies are selling to the druggist at a little less than 18 cents. Some of the small companies are selling the same product to the Government, to the public, and to the drugstores for 2 cents or a little less. So, even though there are three companies, there is really no competition between them. They sell cortisone, they sell hydrocortisone, they sell prednisone, all at the same price. I don't think that is good competition.

Dr. SMITH. Mr. Chairman, I thought we were discussing concentration. I can't talk about prices because of the nature of my work.

Senator KEFAUVER. The reason we brought this up is that you said that there are more than 1,300 companies in this field, with no one company accounting for as much as 10 percent of the total sales, and that it is easy to get into the industry, and so forth.

Dr. SMITH. No more than 10 percent of the total industry sales for any one company.

Senator KEFAUVER. That may be true when you take the overall industry, although we have had statements here to the contrary, but

many of these important products are in the hands of one or a very few manufacturers, as you can see.

Dr. SMITH. It was my hope, Mr. Chairman, in the beginning, that we would be able to talk about the industry, not the individual product, because I think it is the industry as a whole that is serving the public.

I would like to make a request if I could, however, because I haven't had the opportunity to study this table in detail, and some other material that was distributed yesterday, or last evening, which contains a few errors. I wonder if it is possible if we could submit later statements for this last evening's material or this early morning's.

Senator KEFAUVER. Of course you can.

But, before we recess, here is an article by Mr. Joseph McEvilla, assistant professor of pharmacy administration of the University of Pittsburgh, dated January 1958. He says:

> The extent of concentration within the pharmaceutical industry is indicated by the fact that, in 1956, 10 firms had slightly more than 80 percent of total sales. The largest firms has 12.1 percent; the second largest firm had 11.9 percent of total industry sales. While the individual firm enjoys what at first seems a relatively small percent of total industry output, in an industry composed of 1,163 manufacturers where less than 1 percent of the firms enjoy over 80 percent of total annual industry sales, a recognizable degree of concentration is apparent.

You undoubtedly are familiar with this article, which was published in the magazine Drug and Cosmetic Industry.

Dr. SMITH. I am sorry; I don't even know the gentleman. I don't know where he got his figures.

Senator KEFAUVER. We will make this exhibit 234.

(Exhibit 234 may be found on p. 10959.)

Senator KEFAUVER. We will have to stop at this point. I would like to consult off the record for just a minute.

(Discussion off the record.)

Senator KEFAUVER. We will have to desist now. I had asked Dr. Smith previously if some of the distinguished physicians and pharmacists with him had any statements of their own they wanted to give. Dr. Smith said "No"; that they were here only to answer any questions. But Senator Hruska tells me that some of them would like to make a statement, which is not going to be possible at this time, in connection with some matters that have been brought out in the hearings. But, since we know how busy you all are, Senator Hruska and I have discussed the matter, and we think the only alternative is for statements to be submitted by you gentlemen from out of town.

(One statement submitted subsequently may be found on p. 10999.)

Senator KEFAUVER. Dr. Smith, are you here in Washington, and you will be available later on?

Dr. SMITH. I will be available, Senator.

Senator KEFAUVER. I know we haven't covered a great many points which you brought up, and I know that Senator Hruska, Senator Dirksen, and counsel have questions to ask you. But we will have to call you back at a later time, under the circumstances.

I guess, with that, we will have to recess at this time until 9:30 in the morning.

Dr. SMITH. Mr. Senator, may I ask if you expect any of us back tomorrow morning?

Senator KEFAUVER. No, sir. We will have to call you later on. We have out-of-town witnesses in the morning. We only have 1 hour to run, so we will have to call you back later.

(Whereupon, at 10:35 a.m., the committee recessed, to reconvene at 9:30 a.m., Thursday, February 25, 1960.)

(The testimony of Dr. Haskell J. Weinstein, who appeared on February 25, may be found in part 18.)

ADMINISTERED PRICES

WEDNESDAY, APRIL 20, 1960

U.S. SENATE,
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:15 a.m., in the caucus room, Old Senate Office Building, Senator Estes Kefauver presiding.

Present: Senators Kefauver (chairman), Dirksen, and Hruska.

Also present: Paul Rand Dixon, counsel and staff director; Horace L. Flurry, counsel; Peter N. Chumbris, counsel for the minority; Nicholas N. Kittrie, counsel for the minority; Lucile B. Wendt, attorney; Dorothy D. Goodwin, attorney; Dr. John M. Blair, chief economist; Dr. E. Wayles Browne, Jr., economist; Dr. Irene Till, economist; Paul S. Green, editorial director; and Gladys E. Montier, clerk.

(Present at the convening of the session: Senators Kefauver, Dirksen, and Hruska.)

Senator KEFAUVER. The committee will come to order.

Back in February, when we had to delay our hearings because of the civil rights debate on the floor of the Senate, Dr. Austin Smith testified and read a portion of a lengthy statement and put the rest of it in the record. At that time we were in the process of asking Dr. Smith questions with reference to his testimony. That questioning had to be delayed until this time because of the situation in the Senate, and then Dr. Smith was unavailable. So our purpose here today is to continue to discuss with Dr. Smith the statements and exhibits that he has put into the record.

You have with you again, I believe, a number of pharmacists and physicians, Dr. Smith. I think you have identified them before. You brought them with you to assist you in answering any questions which might be directed to them: Is that right?

STATEMENT OF DR. AUSTIN SMITH, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY JOHN K. WORLEY, GENERAL COUNSEL

Dr. SMITH. Yes, that is right, Mr. Chairman. We have an additional member today. Would you care to have me identify him?

Senator KEFAUVER. All right, sir.

Dr. SMITH. This is Dr. William B. Walsh, who is the president of the People to People Health Foundation, Inc., which is sponsoring Project Hope. Dr. Walsh will be available for questioning, too, par-

ticularly in relationship to the industry's support of such projects.

Senator KEFAUVER. Yes, sir. We are glad to have all of these gentlemen here. But your statement has been so extensive that we will direct our questions to you, Dr. Smith.

Dr. SMITH. Well, Mr. Chairman, could I ask a question, please? In your letter of April 18 there is a sentence:

> As you know, your presentation to the subcommittee in February was not completed and the present request is to permit you to conclude your presentation and the subcommittee to conclude its questioning.

Would there be opportunity to complete the presentation, or will it be confined to questioning?

Senator KEFAUVER. We want to accommodate you any way that we reasonably can. I have here three parts of your original statement. I thought this was your entire presentation, and that we were going to ask you questions about all of this. If you have something else you want to present or to put in the record, we will, of course, allow you to do so.

Dr. SMITH. Thank you, sir.

At the end of the last hearings, there were presented some charts on which I asked the privilege to comment at a later date, and you granted this privilege. We are prepared to comment on these charts, and in so doing will provide information which would tend to supplement our statement about the charts, and related information which we feel would be useful to the subcommittee.

Senator KEFAUVER. Very well, Dr. Smith. But try to put as much of it in the record as you can, because your time and our time is limited. We do want to ask you quite a number of questions about some of your statements in the formal report that you submitted.

So whatever you want to state briefly and put into the record, you may do so now.

Dr. SMITH. Thank you.

There are three or four exhibits which at this time I would like to introduce to respond to your invitation in February.

Exhibit No. 1——

Senator KEFAUVER. Our last exhibit was 258; so this will be 259.

Dr. SMITH. No. This is responding to your invitation.

Senator KEFAUVER. We are putting the exhibits in by numbers.

Dr. SMITH. I am sorry. I misunderstood. This exhibit is a placard which describes the industry about which I want to speak, and as I try to answer the later invitation, respond to the earlier invitation of February.

The "3–D industry" is what we have described on this card—discovery, development and distribution.

Now, it has been said during the previous testimony, and particularly since then, that there has not been support of the industry by medicine and by pharmacy.

Our second and third charts will quickly give you some idea of the support which comes, not from individual physicians, but from organizations or official voices of organizations, for example, State medical journals and State pharmacy journals. They can be passed along quickly.

Senator KEFAUVER. That will be 260 and 261.

(Exhibits Nos. 259, 260, and 261 follow:)

EXHIBIT 259

EXHIBIT 259

THE 3-DIMENSION INDUSTRY
DISCOVERY
DISTRIBUTION
DEVELOPMENT
3D

EXHIBIT 260

ANNUAL MEETING — MAY 17-21, 1958 — HADDON HALL — ATLANTIC CITY

THE JOURNAL

OF

THE MEDICAL SOCIETY OF NEW JERSEY

Entered as second-class matter September 6, 1904, at the post office at Orange, New Jersey, under Act of March 3, 1879

Vol. 55, No. 1 JANUARY, 1958

THE JOUR
OF
THE MEDICAL SOCIETY

Editorials • • •

Brand Name I

More than 85 per cent of all prescriptions are prefabricated by the pharmaceutical manufacturer. They are not compounded by the retail druggist. Thus the integrity of the manufacturer becomes as important today as the honesty and cleanliness of the retail pharmacist was in 1900. Modern mass production, whatever its disadvantages, does guarantee standardization. One spoonful of a good brand's Elixir XYZ has the same composition and potency as another teaspoonful of the same brand's Elixir (if you use the same teaspoon). This is not true of a fly-by-night manufacturer of shoddy merchandise. But it is true of any of the reputable manufacturers who advertise in this and other physician-controlled journals.

Control is the secret of sound manufacture —control of purity, viscosity, solubility, potency, vehicle and particle size. To exercise control at every step of the manufacturing process is expensive. A manufacturer who ignores controls can sell his product cheaper. It may be announced as a "pharmaceutical-pa-

Publication Monthly Since 1904
Under the direction of the Committee on Publication
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Vol. 55, No. 1 JANUARY,

VOLUME 55—NUMBER 1—JANUARY, 1958

69 projects. His purpose, to be sure, is not charitable. He expects it to pay off, hoping to make enough profit on the one successful experiment to pay the workers on the 49 wild goose chases. Still, if an unethical manufacturer can borrow the results of that research, he can undercut the original maker in price; the second company doesn't have to pick up the research tab. Hence, the by-passing of good brand-named products is a body blow to research. Why should a company spend millions in research to see their final products left on the shelf in favor of a cheaper substitute?

Chemically speaking, one antacid tablet may be the same as the other. Still, if you are chewing the tablet, you prefer the one of it a smooth taste to one that tastes and seems like a mixture of grit and chalk. And if you prefer the brand-named, more elegant tablet, your patient is entitled to it too.

A suppository that melts in the container before use—or fails to melt in the body cavity during use—is worthless no matter how cheaply it can be bought. Melting point control requires expensive equipment, and adds to the retail price. A first-class manufacturer, however, will not put out a suppository without a controlled melting point. A third rate manufacturer may do so. And he can sell it cheaper.

So the experienced physician is not defensive about prescribing brand-named products —or giving the retail pharmacist a choice of reliable brand names. He knows that the patient can buy an ersatz product a little cheaper. But precious things don't sell at cut-rate prices.

"Ancillary" is a Fighting Word

Officially you may call the organizations of doctors' wives an "auxiliary." But as an individual, no wife will let you dub her "auxiliary" to anything. She's not a subordinate or peripheral part of your life. (Anybody want to argue with us about that?)

Another fighting word is "ancillary." It is from the Latin for "handmaiden." The essence of being a handmaiden is being subordinate, subservient or servile. From the viewpoint of the lone physician taking full responsibility for a sick patient, from his viewpoint, the laboratory and the x-ray department are, perhaps, "helping" him; and so are those "ancillary." But they are not, "servile."

Except for mild fibrosis in the office, most patient-care today is a team function, with the practitioner serving as a captain. The nine men on the ball team are all needed. Their functions are different, but you would scarcely call the short-stop servile to the pitcher, the left fielder subservient to the third baseman, or the pitcher ancillary to the field captain. Whether a "non-physician" can be an equal member of the team is an arguable point—let's save that for another day. But the physicians on the team are all brethren and are not to be scheduled along a pyramidal hierarchy. "The pathologist, radiologist, anesthesiologist, physiatrist, resident and consultant are distinct cogs of medicine each making a unique and precious contribution to a common goal. The family doctor or the treating physician has the sworn responsibility for final decision. Those who help lighten his labors and help divide that burden are his colleagues, not his servants. Let us anticipate that unfortunate word "auxiliary" and place it (with "brand spectrum," "grass roots" and "armamentarium") in the grave-yard of useless clichés.

Publisher's Memo

[redacted] IN THE LAST MONTH OF [illegible]

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Articles for publication and all co should be addressed to the Editor's Victor Boulevard at Brookside, N

GP February 1960

More and More People

WE recently heard some fascinating population statistics. They aren't of a nature that pose an immediate threat but they are more colorful than simply pointing to the increase in life expectancy.

If the population of the world continues to increase at its present rate, approximately 18 per cent per decade, in 720 years there will be one person for every square foot of dry land. That makes for crowded conditions but life won't be nearly as rough as it will be 1,700 years from now—when the aggregate weight of the people on earth will equal the weight of the earth itself.

As a clincher, statisticians point out that if our present birth rate dated back to the time of Christ, we would now have 50 million people per square mile. Not even New York is that crowded.

If all of this involves a word to the wise, we haven't discerned the message. Perhaps it's another way of telling us that the world of today has a great deal to offer.

We're reminded of stories about [illegible] statistician who drowned in a pond, the average depth of which was only two feet.

The Cost of Drugs

PATIENTS COMPLAIN of the high cost of drugs and often blame the pharmacist. However, the pharmacist is not at fault. Although there may be an occasional case of overcharging, the pharmacist settles for a reasonable profit plus an allowance for overhead and a very large (but necessary) inventory. A pharmacist must stock drugs worth at least $16,000. The reason for the high cost of drugs goes back further than the pharmacist.

Remember, too, that not all drugs are high-priced. For instance one can buy aspirin, still a very useful drug, for as little as $1 per thousand tablets or one-tenth of a cent apiece. Ordinary penicillin, once very expensive, is now the cheapest antibiotic. One can still buy the old drugs such as nitroglycerin, milk of magnesia, and phenobarbital quite inexpensively. It is the new drug which costs money.

The reason is obvious. First of all, a new drug usually follows years of painstaking organic chemical investigation to produce compounds which have some therapeutic application. After that, these compounds are carefully tested on many species of animals to determine the pharmacologic effects and to detect any possible therapeutic implications. During this period (which may take months or years) acute and chronic toxicity studies are done. At the end of this time if nothing of value has been detected the whole program is junked and research again begins from scratch.

Occasionally one or more compounds look promising. These compounds are then submitted to clinical research workers for study on patients. Very often at this stage, the disheartening discovery is made either that the drug is too toxic for man or it does not produce the therapeutic effect predicted by the animal experiments. If such is the case the whole study must be abandoned and [illegible] more the start must be made in the organic chemistry laboratory.

The unusual drug may show considerable promise in the human studies. When such is the case, the manufacturing company arranges for simultaneous clinical trials throughout the country. Substantial grants to hospitals and medical schools are made. Finally all the data are assembled, and the company files a new drug application with the Food and Drug Administration. Once approval has been obtained, the manufacturer must now inform the doctor about the new product.

This is done by advertising, distribution of samples and reprints of [illegible] by investigators of the drug.

It should be plainly evident that the development of a new drug is a very costly procedure, often running into several million dollars. This

Editorials

cost must be met and must appear in the actual cost of the drug to the consumer. Thus in contrast to aspirin which, as indicated previously, can be obtained for one-tenth of a cent per tablet, the new drug per tablet or capsule must cost the patient anywhere from 40¢ to $1 each—sometimes even more.

The doctor in prescribing for his patient, particularly one in the lower income brackets, should keep in mind the cost of drugs. He may be able to give the patient phenobarbital instead of the latest tranquilizer; he may be able to advise aspirin for joint pains rather than the newest analgesic or anti-inflammatory. The newest is not necessarily the best, and the judicious use of established U.S.P. drugs can save your patient a lot of money. Remember, however, that there are times when a new drug must be used as a lifesaving measure. In that case, the cost of the drug, whatever it may be, is a minor consideration in relation to the life of the patient.

Progress in Endocrinology

MODERN advances in medical diagnosis and therapy appear with such extraordinary rapidity that what one writes today is often archaic tomorrow. The rapid progress being made in therapeutics is usually transferred to the physician's armamentarium at a much slower rate and as a result, there is a significant time loss before the drug is available to the physician in private practice. This is perhaps seen with greater frequency in a specialty such as endocrinology than in many of the other branches in medicine. Many times, the physician busily engaged in patient care may not be aware of the various ramifications of this highly complicated and interesting specialty. Thus he may not be able to offer his patients the benefit which they would normally reap if direct application of new principles were made as promptly as possible.

In an attempt to bring some of the modern

November 1959

Current Medical Digest
EDITORIAL

COMPETITION IN THE DRUG INDUSTRY*

MORE than 1000 pharmaceutical companies manufacture drugs for our use.† That means a lot of competition, jostling, and duplication. Theoretically, it would seem smarter to consolidate these companies into a single drugmaking unit that would save millions in overlapping costs and avoid duplication of effort. Yet if this were ever done, it would be a massive blow to public health. The competitiveness of the drug industry—which is a drag on the industry's profits—is a boon to our patients and to ourselves.

The most dramatic effect of this competition is the way it keeps prices down. With all good companies making drugs that conform to standard, no one is going to buy Tradename X at 4 cents a capsul when Tradename Z sells at $2\frac{1}{2}$ cents. So competition forces down the price, benefiting our patients.

More than that, competition compels companies to search for different and better ways of preparing an item. If Company A has a patent on a process, Company B cannot get into the act unless its chemists find an equally good but basically different process. So competition spurs Company B's efforts to improve the technique and Company A, anxious to remain in the running redoubles its efforts.

Then, too, competition rapidly makes drugs obsolete. If one manufacturer produces a fine antibiotic with only 3 side-effects, his competitor works to manufacture one with no side-effects. Result: the first antibiotic becomes as obsolete as tincture of gentian. This plays havoc with drug profits but it keeps the best pharmaceuticals in front of the shelves.

Every good company competes with itself. One chemist sweats

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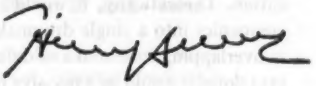
* Reprinted from *Journal Medical Society New Jersey*, March 1959.
† Weilburg John: *Bulletin of the Los Angeles County Medical Association*, May 15, 1958.

Editorial

for years to manufacture a new drug only to see his colleague across the room make it obsolete by finding a better product. Then, too, competition prevents a company from becoming self-satisfied. No pharmaceutical manufacturer can ever rest on its oars.

So let Europe have its cartels, and Russia its state monopoly. We'll take a thousand fiercely competitive companies duplicating each other's efforts, driving each other's prices down, and striving mightily to win the blue ribbon for the most effective, least toxic drug of its kind. It is no coincidence that competitive American drug enterprise has given us the finest pharmaceuticals in the world.



Henry A. Davidson, M.D.
CONTRIBUTING EDITOR

WASHINGTON

by Ernest V. Joiner
Managing Editor
MODERN VETERINARY PRACTICE

Politicians Woo Senior Citizens With Drug Price Probe

With 23% of all 1960 [illegible]

to answer governmental charges with the same thoroughness that characterizes that of governmental investigators.

The affair bears out an approved political stratagem—hit first, hit hard, provoke strong public approval, and shut down before the defense can muster its forces and strike back. This is not to imply that such investigations are not worthy tools of government. However, they are worthy only when conducted in complete fairness, when the defense is adequately prepared to answer, and when the prime considerations are the strength and welfare of our American economy.

Drug firms have been accused by investigators of making "too much" profit on wonder drugs—as high as 10,000% in isolated cases. It is this charge, coming from a respected governmental body, that provides headlines to generate public reaction. In the current hearings, news of the industry's rebuttal material has been found "continued on page 14," without headlines. Any propagandist knows that it is possible to present two sides of a controversy fairly, yet present one side in such a manner that a reader's mind may be completely won over by the time he gets down to the trailing testimony of the other side!

For instance, most daily newspapers reporting Kefauver's inquiry, failed to print this headline, "Drug President Refutes Government Charges." Instead, a sampling of front page banner headlines appeared like this, in essence, "Exorbitant Costs of Drugs Hit." There is a difference between a positive and a negative approach to an impartial news story.

Profit Is a Nasty Word

More and more, the taking of a profit is becoming immoral in the United States. It is fast becoming one of our accepted "nasty" words. This trend is no better illustrated than by pointing to increasing state and national governmental limitations on net profits of industry, such as public transportation and public utilities. This trend is a repudiation of the principle of free enterprise and the theory of capitalism upon which the nation is founded.

Making a profit is not a crime.

A few years ago this editor purchased a plot of ground for $100. Five years later a prospective purchaser offered $1,200 for the same unimproved plot. Had the offer been accepted, would the editor's 1100% profit entitle him to be held up before society as a scoundrel?

Government Only "Profiteer"

The committee has charged one drug firm with selling abroad for 17c, a unit of drugs that retails for about $8.40 in the U. S. This implies, without investigation into the reasons, that a crime has been committed against the people.

On the other hand, the committee has never investigated the fact that a pack of American cigarettes which retails for 30c in the U. S. can be bought for as little as 8c and 10c in Army Post Exchanges and Navy stores abroad. The difference of about 300% is not profit to either manufacturer or seller. It's a profit to the government, and represents taxes on that commodity.

There has been no inquiry [illegible] the fact that a case of good American whisky can be bought overseas for $10, while the same case sells in the U. S. for $60 to $75. Here again, the manufacturer and seller do not harvest this 600% markup. This 600% represents taxes imposed by this government, benevolently removed to accommodate those purchasing merchandise abroad.

Newsman Paul Harvey recently made an exhaustive survey of costs involved in a loaf of bread. Who, he wanted to know, gets the fabulous profits from a single loaf of bread that retails for 24c, when all the farmer got for producing the wheat was only 2c? He went through every step in the transporting and processing of a cup of wheat. He included the standard markup for profit made for every agency that handled it, as well as for profits allowed the handlers of every ingredient incorporated in the one loaf. He calculated railroad transportation on grain and finished products, and noted the profits made by transportation, the bakery, the jobber, and retailer. When that loaf was placed on the grocery shelf, everybody had taken a profit, and the loaf should have sold for 12c.

But it didn't.

NEW YORK STATE JOURNAL OF MEDICINE

PUBLISHED THIS DAY BY THE MEDICAL SOCIETY OF THE STATE OF NEW YORK

MARCH 15, 1960 NUMBER 6

VOLUME 60

EDITORI

Improvement in Standards of Care in

With the number of individuals of age sixty-five and over increasing in the United States at a rate of about 1,000 per day, there is increased need for facilities for the care of the ill and disabled among them. General hospitals are receiving more and more of these aged individuals, and nursing homes are often called on for continued care over a long period of time.

Nursing home operators are sensing their responsibility in providing good care for these people and have organized themselves for the purpose of exchanging information which will result in the raising of standard of care. Their efforts are commendable and are meeting with an apparent degree of success. They are stimulated and encouraged by local and State agencies whose rules and regulations complement the nursing home operators' efforts to raise standards of care in their homes. In many of the larger communities, the local health departments share this regulatory responsibility with the State Department of Social Welfare and may even formulate their own ordinances. These local requirements, however, cannot be less strict than the "Rules and Regulations for Private Nursing Homes" of the New York State Department of Social Welfare.

The Subcommittee on Aging and Nursing Homes of the Medical Society of the State of New York applauds all efforts throughout the State to improve standards of care in

nursing that the for nurs this in seeing them is requires clan e person expro are ac e's an raise t The p medic simila has pa The hous Priv point with tient Ot be of nurs After also com area has tion

Congressional Investigation of the Drug Industry

Committees of the Congress in the public interest have made inquiry into the operations of industry on many occasions—and are now holding hearings on the drug industry. This is the first time that a business

so closely connected to the practice of medicine has been subjected to such scrutiny.

The preliminary skirmishes of the first few days of this investigation developed some unfortunate and misleading headlines—one

New York State J. Med.

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scientific—invested in profits in the therapeutic per cent or [illegible].

Physicians have respect and admiration for the pharmaceutical industry which has made this present era of chemotherapy possible. Many of those who practiced medicine at the time of Oliver Wendell Holmes and later in Osler's time became therapeutic nihilists because of the ineffectiveness of the remedies at hand. Not so now—our materia medica is large, modern, specific, potent, and reliable. We know that responsible members of a fiercely competitive industry with high ideals have made it so. A startling fact is that of every 100 prescriptions written today 90 are for drugs that were not available even fifteen years ago.

We also have respect for the processes of [illegible] government which seek to protect the consumer. But we challenge their play. In the astronomic profit accusation based solely on the cost of raw material, no account was taken of the added costs of distribution, marketing, taxes, and administration. Also unmentioned were the costs of two important operations inherent to the industry, research and education. One dollar out of every nine received from sales is currently going into research—the laboratories must be staffed by highly paid personnel such as chemists, biochemists, pharmacologists, physicians, veterinarians, bacteriologists, virologists, biostatisticians, and the hosts of technicians who serve them. Last year these laboratories worked on 114,000 different substances. Only 1,900 of these potentials proved to be worthy of clinical testing, and eventually probably only 40 of these will become prescription drugs. This is a rather discouraging laboratory success rate of three ten-thousandths of one per cent. Who is there, however, who will not admit that the antibiotics, vaccines, and steroids available today are worth the prodigious effort and expense?

The matter of the education of the prescriber in the use of these products must be given the minute. The brochure for a new drug is frequently the only source of information available to the physician. It must be reliable and detailed. Some of us shudder when the weary mailman dumps the daily load of printed matter on our doorstep, but read it we must for we all do understand the necessity for this educational and promotional material, and there are few of us who do not learn from it something good and useful for our patients.

We who are more than merely interested bystanders at this investigation expect to see all the facts presented fairly and dispassionately and a just conclusion arrived at—one which will be worthy of our democratic free enterprise system.

Chiropractic

It is hardly conceivable that a responsible legislature of the State of New York would pass the current chiropractic bill. For years the Medical Society of the State of New York has opposed licensure for chiropractors on the ground that the cult has no valid scientific basis. If the legislature were to license them in this State it would be tantamount to the perpetration of a fraud upon the people, since the cult would be just as unscientific when licensed as it is now unlicensed. Furthermore, if licensure were ever granted it would appear to place the weight of approval by the State behind such practitioners to the detriment of the public health.

There are many reasons why chiropractors should not be licensed. Chiropractors endanger the public health because they do not believe in the well-established, scientifically proved, and publicly understood germ theory of disease. They claim they can prevent and cure infantile paralysis, tuberculosis, diphtheria, scarlet fever, pneumonia, syphilis, gonorrhea, and other contagious diseases by their so-called "manipulation of the

March 15, 1960

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Drug Prices to be Probed

Mark it down that the U. S. Senate will go into a full fledged investigation in 1960 on the costs of pharmaceuticals. Senator George A. Smathers of Florida has introduced a resolution calling for hearings before the Senate's "Select Committee on Small Business" and he has the endorsement of Senators Lyndon Johnson, Warren G. Magnuson and Frank J. Lausche in support.

The pharmaceutical industry, both by individual companies and through trade agencies like the Health News Institute, is launching the counter offensive of facts even before the battle starts in statements explaining why drugs cost what they do.

The most telling statistic we know is that 20 years ago the public spent 4.7 per cent of its disposable income after taxes for medical care (doctors, hospitals, dentists and drugs). Today it can be shown that 4.6 per cent of this same disposable income goes for this purpose.

In a world of changing buying power that the percentage cost of treating illness keeps its same relative position.

The simple fact is that to the public and to any individual patient, the cost of illness involves the three elements—doctors of either medicine or dentistry, drugs and hospitals. We repeat this axiom because there is a tendency (by the medical profession, by hospitals and by pharmaceutical manufacturers) to try to "get off the hook" by claiming the others are to blame. We think this is wrong and that all three elements in the problem of illness have to stand together and assume joint responsibility.

It is all too easy, and some doctors do it, to note the true fact that medical care costs (the payments to physicians) have not risen nearly as much as the costs of hospital care in a relative sense. On one [illegible] the average price increas[e] thing; 145 for medical [illegible] pitals over the base of 10[0] cal pharmaceutical indus[try] finger at hospitals, too.

Similarly the drug h[ouse] point the finger at the hospitals can blame [it] plus the swift rise in personnel.

We feel it is wro[ng] to argue that the worry and no re[al] costs or drug cost[s] wrong if hospita[ls] responsibility abo[ut] icians' fees or t[he] e same applie[s] fession and to [oth]ers in relati[on]

It has been it, that it is [the] proach to th[e] Admit that lars than it applies to should re[ceive] each doll[ar] good tact[ics] tive fact[s] public [illegible] same p[ro]blem The bl[ame] vastly testify[ing] 1920 of li[fe] for

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too high or any other commodity of service too high?

As a free-enterprise system of capitalism, the United States has an automatic, built-in deterrent when something becomes too high. When it really is too high we stop buying it and the price drops in the face of competition.

Certainly this is true in the field of medicine for any physician can easily price himself out of the market for his services. If the doctor wants $300 for an operation that an equally good man will do for $200 he soon finds that the laws of economics apply very swiftly. And the same applies to the price for house visits, consultations and on and on.

Is the cost of health care too high? By all economic yardsticks it is not; not while more and more people buy more and more insurance for more premiums to pay their bills for illness; not while people demand more and more services from hospitals and will pay for them; not while patients demand more and better care from their physicians and will pay for this improved service.

What the battle is all about is that more and more people are getting trapped in the easy credit system of today and are committing their income on installment buying of TV sets, electrical appliances, automobiles and the thousand and one commodities which are part of our high standard of living. If they can find dollars to buy the most advanced model of hi-fi stereophonic sound and get these dollars out of their regular yearly medical hospital and drug expenses, then they can have the dollars from the golden goose and kill it too. Maybe that is what they want to do and we don't blame them for trying. But somewhere and sometime they will have to draw the line of [illegible] where they spend their income.

We believe the drug companies, the hospitals and the medical profession should all work together and explore every avenue to reduce the cost of illness to its lowest possible level consistent with the new and best knowledge and application of how to do this. But we also believe that there need be no crawling, no apology, or no cringing retreat in any explantations on the cost of being sick. ◄

NOVEMBER 9, 1959

Editorial Page

Pharmaceutical Prices

The Kefauver hearings, although politically inspired, have made it necessary for the pharmaceutical industry to explain and defend its pricing policy. The hearings have struck a responsive cord in the minds of the public. The ever-increasing spiral of the cost of living, due to the failure of the government to balance the national budget, has made the average man acutely aware of the overall cost of medical care. Since the cost of drugs is so intimately and apparently indistinguishably associated with medical care, at least in the public's mind, in all probability physician's fees will also come under attack.

Any proposal to police pharmaceutical prices poses a potent threat to our entire free enterprise system. In a field as highly competitive as pharmaceutical manufacturing, profit expectations must be sufficient to repay the cost of research and provide a fair return to investors. Millions of dollars may be spent on rescarch and clinical investigation before a new product can be marketed and returns begin to be realized on the enormous investment. In many cases, due to rapid advances in research, the product is obsolete before it hits the market, and the entire investment is lost. Research pharmaceutical houses are dedicated to a policy of continuing endeavor to produce better drugs as rapidly as safety permits, even when such progress destroys the market for some of their own products, long before their full potential sales have been realized.

Not only is it desirable to recover the original costs, as well as a profit commensurate with the risks involved, but additional funds must be forthcoming if pharmaceutical research is to expand for the maximum ultimate benefit of mankind. The price placed upon drugs, particularly antibiotics, antibacterials, and hormones, of necessity, cannot be merely the cost of raw ingredients. Research, clinical investigation, advertising, and early obsolescence, are all important and costly considerations. If the practicing physician is to be made aware of the virtues of a new drug in as short a time as possible, intensive promotion: advertising in medical journals, exhibiting at medical conventions, personal calls on physicians by professional service representatives, and grants in aid to both private physicians and clinics to firmly establish the efficacy and safety of the new product, are all necessary.

The pharmaceutical companies enjoy little direct relationship with the public. Their friends and allies, the druggist-pharmacist and the practicing physician, because of their daily intimate contact with the public, are in a most advantageous position to point out that the price of research pharmaceuticals, since they greatly shorten illness, are not really expensive. More rapid recovery and the prevention of death, leading to the prolongation of life, make the new near-miracle drugs truly inexpensive.

If the pharmaceutical industry and the medical profession cannot deter the government from interferring with prices and fees of private enterprise, and assuredly both medical service and pharmaceuticals are among the most private of American enterprises, then the days of free private action in all professions and businesses are numbered. For the power to arbitrarily determine prices and fees, is the power to absolutely control or even destroy. The American public should be made to realize the incredible progress in the last few years of both the medical profession and the pharmaceutical industry, is not the result of government control but of free enterprise.

Let us not cripple with ill-advised legislation the economic system that has made America the mecca of the world.

F. P. Rhoades M. D.

Reprinted from the January 1960 issue of the Michigan and Wayne County Academies of General Practice BULLETIN.

Daily News
THE AMERICAN ACADEMY OF GENERAL PRACTICE

Published Monday, March 21, through Thursday, March 24, during the 12th Annual Scientific Assembly of the American Academy of General Practice which is combined this year with the Philadelphia Postgraduate Institute. Copies may be obtained in the lobbies of key hotels where Assembly guests are registered and the Registration Area at Convention Hall.

News items may be submitted at the Press Room, Bellevue Stratford Hotel, or call Miss Cleo Norris, AAGP Daily News office at Dunlap Printing Company, LOcust 4-3825. Items must be submitted by 3 P.M. prior to the day of publication.

March 23, 1960 Third Edition

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No Pharmaceutical Gap

The 138 manufacturers of pharmaceutical preparations in this country, together with 9,000 hospitals, 53,000 retail pharmacies, and 160,000 practicing physcians are part of a miraculous team. Out of this intricate mixture of public service and profit there emerges the proposition that never has any people on the face of the globe had a greater medical care bargain than Americans.

Hand in hand with private practicing physicians, the pharmaceutical industry has spent nearly a billion dollars for research in the past decade.

Behind every new preparation there is an average investment of $2 million. Successful companies have made profits for the stockholders who advanced the capital to finance such bold enterprise.

Surely there is no finer example of enlightened capitalism in the world than is to be found in the records of the familiar company names making up this great industry.

There has been no missile gap in pharmaceutical research in America!

—Mac F. Cahal
Executive Director, AAGP

VIRGINIA MEDICAL MONTHLY
(Founded by Landon R. Edwards, M. D., April 1874)
PUBLISHED MONTHLY BY THE MEDICAL SOCIETY OF VIRGINIA
1606 HOVER ROAD, RICHMOND 21, VIRGINIA

The Virginia MEDICAL MONTHLY

April, 1960
Vol. 87, No. 4
Whole No. 1295

Guest Editorial....

Watch Out!

IT IS QUITE POSSIBLE the powers that be in Washington have more than one reason for complaining about the prices of drugs. Senator Estes Kefauver's drug price investigating subcommittee would have us believe that the government's sole interest is "simply with the price of drugs—a price which must be paid by someone under any system of medical care". I think there is a psychological reason which they hope to keep under cover. This Senate antitrust investigation is just another cunning approach in the attempt to slip socialized medicine in at the back door. It appears to me that Mr. Kefauver almost gave this fact away in his opening statement when he said: "It is not the purpose of these hearings to question in any way the American system of private medical practice." I react to this statement in the *same manner* I would if a small boy should rush into my office and exclaim: "Doctor, someone batted a baseball through your back window—and I don't want you to think that I did it."

If these investigators' thoughts were just in the drug field, they should also be concerned about quality as well as price. They certainly have shown a lack of interest in the cost of pharmaceutical research and manufacturing, and without research drugs would soon degrade in both quality and quantity. The Senator's line of reasoning in advocating that druggists be allowed to use generic instead of brand names, would throw the drug business into a tail spin within a short time. If one company spends a million dollars to produce a new drug, and another converts is allowed to copy the formula, pay none of the research cost, and market the product at a low price, the results would be disastrous. The latter firms would go broke, initiative to find new drugs would be smothered and we would find ourselves advancing in reverse—back towards the "calomel and castor oil days".

I feel that these governmental probers are motivated, primarily, for publicity. If they can attract enough attention by their investigations of the major drug manufacturing firms, and lead the American people into believing that the prices of drugs are too high, it might be possible to gain a large number of sympathetic listeners.

They hope to stir up enough interest in the drug controversy to swing the spotlight away from the doctors for a while, give us a breathing spell, make us feel complacent and lessen our vigil against legislation like the Forand bill. It is their wish that we don't get wise to their twofold purpose of these investigations in relation to the Forand bill itself. First, they will attempt to convince the lay public that older people, on social security, will not be able to pay the high drug prices—and that the government should step in to help. Second, if these tactics could get a Forand type of legislation passed without enough medical publicity to stir up strong opposition—they would be in position to widen social security to cover everybody. Then we would have socialized medicine under another name.

People, consciously, or unconsciously, associate drugs and physicians together. An aroused populace against drug prices would not be too friendly towards the medical profession. Such a situation would gain recruits for a more effective battle against the free practice of medicine. While we sit on the side lines, apparently unmolested, and watch the steam roller attempt to crush the drug firms, we must remain alert. We could get caught napping like Hitler did one time during World War II—when the Allied soldiers were issued heavy, long-handled underwear. As soon as the Germans got wind of it, they rushed up to Norway while our troops poured into Africa. It behooves us to watch out for all sorts of misleading tactics, because this drug battle is only a sham attack. The medical profession is their chief objective. They hope to find time to reorganize their forces, turn upon us without warning and launch a surprise attack where and when we might least expect it.

Floyd, Va.

F. CLYDE BRESSEE, M.D.

Volume 1
Number 2
February 1960

Mississippi

• EDITOR

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ORIGINAL PAPERS

Mr. Kefauver, Drug Prices, And Common Sense

I

Senator Estes Kefauver, a Southerner by accident of geography and a liberal almost without a peer, conducted a pharmacological circus at Washington during the second week of last December. As ringmaster of the Senate Antitrust and Monopoly Subcommittee, he tried to make the American pharmaceutical industry jump through hoops. As a propaganda performance, the hearings were successful, as to factual findings, issues clicked remain to be judged.

The December hearings were the first in a series, according to Chairman Kefauver, on pricing practices in the drug industry. The subcommittee's rightful interest is not how high or low drug prices are but whether conspiracy and collusion in fixing prices exists among manufacturers or not. As it really was, the hearings were more than a public flogging of the American pharmaceutical industry. The subcommittee's staff economist, John M. Blair, accused manufacturers of making profits up to 7,000 per cent above basic costs. Unfortunately, the accusations got more headlines than the drug companies' replies.

II

No drug manufacturer should be defended simply because he makes medicinals. In the first place, if his product or pricing practices are manifestly bad, the free market soon rectifies the situation. A vast majority of American physicians prescribes only those tested, quality preparations indicated for proper treatment in minimum quantities required at the lowest possible price available. The same vast majority of doctors has no interest in pharmaceutical manufacturers other than in sharing the universal desire for more and better medicinals at fair, competitive prices.

The Mississippi State Medical Association has this same interest and none other. It owns no drug stocks, holds no patents on formularies or proprietary compounds, and—like the doctor—is trying to work itself out of a job by seeking only successful treatment of disease and injury. M.S.M.A. has

But Mississippi physicians and their [illegible] medical association insist upon the game being played fairly, with all ground rules observed and everyone given an equal opportunity at bat.

making for $4.80. Asked by her son-in-law if she thought it was worth the money, the lady wisely replied, "It's worth it if it works."

In 1958, the average prescription cost $3.08 but there is more to it than an average price paid. By no means does this explain away recurring drug costs incurred in long-term therapy nor the occasional Rx with a $15 price tag. But there is a far greater significance to the true cost story.

In 1928, lobar pneumonia fluttered a pall [illegible] in the hospital for four to five weeks. The mortality was about 33 per cent. With all care expenditures considered together with loss of earnings, as much as $1,000 was involved for those fortunate enough to be spared funeral expenses.

In 1960, the ordinary case of lobar pneumonia has a duration of less than two weeks and usually requires no hospitalization. Antibiotics or broad spectrum chemotherapeutic agents run between $15 and $30 for adequate care of the case. Of course, the physician's fee is proportionately less than in 1928 because of the shorter care duration. And mortality is now only slightly more than 3 per cent.

As recently as 1940, Children's Hospital at Boston reported 305 cases of mastoid abscess. Painful surgery with long aftercare did well to preserve life and often left impaired hearing. Because of antibiotics, some young physicians today have never seen a mastoid abscess.

V

Martin emphasizes that there's a great difference between *costs* and *expenditures*. The former is the amount which must be given in exchange for a unit of a good or service. The latter is the total sum laid out for the number of units purchased. Mr. Kefauver's staff economist gives little evidence of understanding this fundamental tenet of basic economics.

During the past 30 years, expenditures for drugs have increased as have expenditures for food, clothing, housing, automobiles, and tobacco. But the important aspect to recognize and identify in the drug portion of medical care costs is that the American public's outlay for medicine is proportionately the same today as it was 30 years ago. And look what that share of the health dollar is buying when put to use in the hands of today's physician.

As likely as not, there'll be further hearings on drug prices during the present session of the Congress. There will be more accusations of fantastic profits despite the fact that drug manufacturers enjoy earnings merely comparable with those of other prosperous [illegible] corporations.

There will be attacks on the drug industry's advertising practices which if abandoned tomorrow would drop prices only three cents per therapeutic unit sold. But the gimmick is that there would be fewer and fewer competitive products and unit costs would inevitably rise above present levels. Advertising is the life blood of an industry whose products are predestined to obsolescence [illegible] they are marketable.

[illegible] complaining about drug prices, physicians' fees, hospital costs, and the price of everything are the same factions which would have the federal government practice medicine, construct public housing, and exercise total paternalism—as long as the tax dollar and national credit holds out.—R. B. K.

So They Got It Wholesale

Failure of one of the Lloyd's of London affiliated insurance companies, British Commercial, may drag almost a hundred American physicians into bankruptcy along with it. They are among 4,000 who purchased professional liability insurance from "... Lloyd's of London and/or other companies" because it was priced below coverage offered by domestic carriers in the United States.

In California, at least 17 suits alleging malpractice have been filed against physicians whose liability coverage was un-rewritten in part or whole by British Commercial. Another 50 suits against similarly underwritten doctors are pending. One $80,000 telegram has already been lost and is now being applied to the physician-plaintiff's only insurance is from the solvent British Commercial. From 1953 to 1956, the scientifically elite American College of Physicians offered bargain prepaid malpractice coverage by British Commercial.

Three years ago, M.S.M.A.'s Board of Trustees declined a proposal for group professional liability coverage by "... Lloyd's of London and/or other companies." Subsequently, the Board gave Mississippi physicians the best advice they've ever had on purchase of this coverage—it's worth repeating here and now.

The Journal
of the
Louisiana State Medical Society

$4.00 Per Annum, 35c Per Copy
Vol. 112, No. 3

MARCH, 1960

Published Monthly
1430 Tulane Avenue, New Orleans 12, La.

Pulmonary Function Studies*

• The value of these studies is thoroughly explained, together with their limitations. The author gives eight illustrations.

Editorial

Drugs, Doctors, and Politicians

"Economics is a dismal science." This, in effect, was said by Carlyle over a century ago, and it is even more true now. We see before us the spectacle of politicians advocating free hospitalization for retired Social Security beneficiaries at the taxpayers' expense, criticism of the rising cost of medical care, for which these same politicians are in part responsible, and complaints against the costs of drugs, which are the most effective in all medical history.

The public interest in the price of drugs has recently been attracted by the sensational charges before the Senate Subcommittee on Anti-Trust and Monopoly. There it was stated that the profits were excessive and prices were completely out of line on certain items that various pharmaceutical houses produced. The executives of some of the major pharmaceutical houses were subjected to a sort of inquisition as to why the prices were what they are and what salaries were made by these leaders of one of the world's most important industries.

The manner of presentation, the superficiality of the charges, and sequence in timing in relation to the agitation for the Forand Bill, and the fact that it is an election year, all suggest that there is a plan behind the whole picture. The idea might be to present a tax supported plan as a campaign [illegible] for the battle against State Medicine in Congress in the area of partisan politics.

Since the charges of excessive cost of drugs have been made, it behooves us as physicians to interpret the economics of this situation to our patients and to the public. Inflation is responsible for about 20 per cent of the increase in the cost of drugs, while all items of consumer spending averaged together have increased 23 per cent since 1947. Although drugs have become more expensive in some instances, the need for drugs has been slightly reduced. In other words, each dose accomplishes more. In the distribution of the medical care dollar, medicines and appliances took 25 cents in 1949, and only 26 cents in 1958. The increase in cost has [illegible] of profit to the local druggist. Authoritative investigations

EDITORIAL

have shown that after taxes and all other overhead expenses, the net profit out of every dollar the drugstore receives for prescription medication is less than 3 cents.

In the Congressional investigation referred to above, the major accusations were against the large pharmaceutical houses. Various charges were made that the big houses sold to the government cheaper than to the druggist; that the drug cost less in foreign countries than it might cost here; that one firm made a profit of 7,079 per cent on a new drug combination; that the promotion, sales, and distribution costs were too high and, in substance, that the pharmaceuticals were for profits and not for patients.

In order to answer these several types of criticisms, a general statement of the position of the pharmaceutical industry would be helpful. Elsewhere in this issue is a general review by a prominent worker in that industry.

Next, it must be stated that in order for medicine to have drugs with which to work, manufacturers have to conduct their affairs in such a way as to be able to stay in business. This means they must show a profit, and in order to show that profit they must have conducted research in order to find drugs which may be helpful. Having done so, they must go through an involved procedure of proving, testing, and sales promotion before distribution to the patient can provide any benefit to him. Involved in this process are two enterprises, both expensive and necessary.

One is research to discover and prove the value of a drug and the other is the presentation of the drug to the physician in order that the public may eventually benefit from it. The physician must learn of the drugs through the medical communications of the pharmaceutical industry before he can direct them to the patient. The facts about the drug are promoted through trade advertisements, but principally, by personal presentation. Approximately 90 per cent of the one million six hundred thousand prescriptions which are filled each day could not have been prescribed ten years ago, because they did not exist. Therefore, what the physician knows of 90 per cent of drugs in current use must have been learned in the last ten years in such ways as the industry made available to him.

Competitive conditions in the industry have stimulated the various houses to their utmost in research and production of remedies. A certain phase of medical research has shifted from the medical schools to the pharmaceutical industry. The industry allocated one hundred and ninety million dollars to research in the current year. The result of these expensive researches is by no means predictable. It is ev[illegible] that a large p[illegible] of the exp[illegible]ures in any field will be unproductive. The net result, however, that we have the most effective drugs and are advancing at the most rapid rate of any time in history.

Answering the contention that the pub[illegible] pay too much for what it has received, many facts are to be considered. One of the first of these is when and in what guise outside of socialism is the federal government to undertake to say what the profit from a enterprise should be. Again, dividends per share in the largest pharmaceutical companies vary from 0.5 per cent to 2.7. An inquiry to seven of the most important houses brought out the fact that they were allotting from 1.3 to 15.7 million dollars per year for research, and this represented from 50 to 300 per cent of the annual dividend of the respective companies. The average for the pharmaceutical industry as a whole, was about 13 per cent net profit after taxes. This compares favorably with the general average of stable national American corporations, which runs from about 11 to 16 per cent.

These figures prove that the prices of drugs are not out of line. The critics fail to take into consideration that the cost of the drug must include: research, fail-

THE JOURNAL
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1. Ingalls, T. H.: Common Misunderstandings About Congenital Malformations, A. M. A. J. Dis. Child. 96:182-1
2. Pitt, D. B.: Congenital Mal M. J. Australia 1:855-859 (Feb. 2
3. Wood, H., and Parker, G.: M. J. Australia 1:61-63 (Jan. 23)
4. Abramopoulo, L. J.: Virologi nancy, South African M. J. 32:1-3

be read in its entirety so that misunderstanding of the intent of the message does not arise.

Drug manufacturing in the United States is unique. For years it has offered more benefits to patients of physicians than in any other country. It has contributed immeasurably to the welfare and economy of people in this nation and elsewhere in the world. It has supported research to the tune of millions of dollars, the exact amount never having been determined. Its directors have developed an increasingly deep sense of public consciousness. It has become indoctrinated in recent years to the meaning of medical science in a way that has resulted in even some of the country's best scientists joining the industry as researchers and consultants. And it operates under a combination of legal restraints and voluntary control that has been the subject of discussion in countries throughout the world.

Obviously this means that aggressive selling is certain to occur. In a free enterprise system such as exists in the United States where there is competition and a need for some return for shareholders one finds evidence of such selling in any industry whether it be the manufacturing of cars, appliances, clothing, or foods. The problems that arise in the promotional field stem usually from failure to distinguish between aggressive selling and permissible puffery on the one hand and downright deception on the other. So far as drug promotion is concerned a reassuring balancing factor enters the picture; it is the training and intelligence of members of the medical profession. They are taught from student days and through experience to study, observe, and criticize. Credit for this training should never be overlooked.

Most drug manufacturers are aware of the average physician's tolerance and respect it. If they fail to do this their shortsightedness becomes evident in studies and reports which flow across the desks of their executives. Some people in any field, of course, are interested solely in a "fast buck" and these, unfortunately, bring discredit to their colleagues. The majority, however, are not interested in marketing drugs that serve no useful purpose, as they are too difficult to sell profitably. Sometimes, though, these drugs are made available simply because they are requested by practitioners to meet special situations. Nor do they as a whole bring pressure on investigators to report only that which is favorable. A manufacturer who does this risks public condemnation at meetings. Nor are most manufacturers interested in help from inept investigators. Such help leads to difficulties from the time a new drug application is filed with the Federal Food and Drug Administration until it is marketed. And in reference to marketing, most companies who sell products intended only for prescription use are not anxious to carry advertising to the public. This has been tried a few times, and the spanking from the medical profession was promptly applied and obviously effective.

One of the problems of communication between announcement of a new drug and the distribution of unbiased comment on it has always been the question of time. To be of added assistance to the medical profession the Council on Drugs of the American Medical Association has developed an educational program evident in almost every issue of THE JOURNAL. The statements published by this Council are brief, concise, and clear, and if there is doubt in the mind of any physician about any drug he can always write to the Council office at A. M. A. headquarters for information.

There are times when a proposal is [illegible] the [illegible] practices that can be controlled by nongovernmental intervention. There already is an outcry against too much government regulation, and to permit practices that encourage more such control is in the long run suicidal economically and otherwise. Therefore, if the drug industry is erring in its aggressive selling it should police itself and not encourage a federal agency to assume this responsibility. In this respect it is interesting to recall the suggestion some time ago from representatives of the drug industry for a survey by the American Medical Association to determine how the industry can best serve the profession and to outline the areas of mutual interest and those in which problems may arise. This study, which is based on depth interviews, has been under way for several months and will not be completed for several more. Its possibilities, of course, are exciting to contemplate and its effects can be far-reaching. Important also, however, is the fact that an industry which has made so many contributions is anxious to learn how to make more. This is the way it should be in the American way of life.

ASIAN INFLUENZA AND THE MEDICAL SOCIETY

In this issue of THE JOURNAL (page 891) there appears the second comprehensive report of the American Medical Association Special Committee on Influenza. While the first report (THE JOURNAL, September 28, page 358) was directed primarily toward the individual physician, the present report is intended to be more of a guide to assist local medical societies in organizing their Asian influenza program. At the same time, it offers the means for the medical society to assume its share of the leadership in this particular preventive medicine program.

Despite all previous public press concerning a possible influenza epidemic, an occasion might well arise where local circumstances will necessitate supplemental health education, limited to a particular community or area. For example, local problems are apt to present themselves in regard to the closing of schools, whether certain local groups should receive priority immunizations, and especially how to treat oneself in an unusual home environment. These factors, and many others, should

HOSPITAL FORUM

An Editorial

THE DRUG PROBE

Senator Estes Kefauver (D.-Tenn.), directing his Senate Anti-Trust Subcommittee in an investigation of "*fair* pricing practices" in the pharmaceutical industry, has caused political and public agitation that could pose a threat to the heart of America's health system—the hospital.

How much of the investigation's charges are justified cannot yet be determined. But the *net* result, as reported in the *Kingsport* (Tenn.) *Times*, "will be to shake public confidence in the drugs that the doctors prescribe, in the doctors, and in the hospitals where the drugs are dispensed."

Investigations in the public interest that go behind the facts on both sides of the question are very commendable and certainly would be welcomed by ethically operated hospitals as they would be by ethically operated drug houses. But, as was pointed out in a recent *Detroit News* editorial, the standard approach of Senator Kefauver appears to be: "We know the answers; all we need are facts to match."

Pharmaceutical Manufacturers Association president Dr. Austin Smith said, "To seek the facts is laudable. But to prejudge or to *err* by depending in part on meaningless or questionable figures which may project a confusing, even distorted, picture of a subject that under the best circumstances is closely related to easily disturbed emotions is unfortunate."

One of the greatest problems facing both the medical profession and pharmaceutical manufacturers is lack of public appreciation of the giant strides that have been taken in medical care and drug therapy.

A study by Dan Rennick, editor of the *American Druggist*, shows that at least 78 per cent of all drugs prescribed today were not even in existence 10 years ago.

Since the turn of the century, 25 years have been added to the normal life span of people in this country. The 190 million dollars spent annually by pharmaceutical manufacturers for medical research have made a large contribution to making these "extra" years of life possible.

How ironic that this industry should be criticized for the financial plight of millions whose very lives may have been saved by the industry's vast contributions to medicine.

Certainly every effort should be made to keep the price of drugs at a reasonable level. But unless Senator Kefauver wishes to suggest that the pharmaceutical industry be nationalized, the price of drugs must have some relation to the cost of developing and producing them.

Speaking out in support of the drug industry, the *San Jose News* said, "No one as yet in this capitalistic democracy has established what is a fair markup. If Congress has in its head the notion of legislating on what percentage of profits is reasonable, then this is a step toward socialism of the most remarkable and unprecedented order."

If an example is needed as to which is more medically productive—free enterprise or socialistic control—the Russian pharmaceutical industry is a showpiece. "In the 42 years since their October Revolution," reports John T. Conner, president of Merck and Company, "Soviet science and technology have been unable to come up with a *single* major drug discovery."

Concentration of the business in pharmaceuticals is far less than in other industries acknowledged to be competitive, such as automobiles, steel, aluminum, and food. Out of an estimated 2,000 firms engaged in the business, no single drug manufacturer has as much as 10 per cent of the market.

Unfortunately, staff investigators of the Senate subcommittee have singled out some drugs which would appear to have unnecessarily high markup even when research costs of the product are taken into consideration. However, last year the industry's laboratories worked with 114,600 different chemical substances; 1,900 of these showed enough promise for clinical testing; but less than 40 of them will ever become prescription drugs. Sales of the 40 must somehow bear the cost of the 114,560 failures so that "next year" more research and new discoveries [illegible] for a longer and healthier life.

Hospitals have a major stake in the current investigation of drug pricing practices. It is vital to the preservation of the hospital system as it is known today, that the public understand all that is involved in the high cost of medical care and, what is probably most important of all, that this country's general good health and long life is the direct result of free enterprise in health care. ■

Some men grow,
Others just swell.

Gloomy Gus

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CLINICAL PHARMACOLOGY and THERAPEUTICS

volume 1 number 1 January-February 1960

Safe new drugs and their control under law

It has been our aim to review briefly Food and Drug Administration's methods in evaluating new drugs, and it is our hope that this will provide a better understanding of the role and function of the Food and Drug Administration in its regulation of new drugs. This will, in turn, assist physicians to meet their responsibilities in this important field.

William H. Kessenich, M.D. *Washington, D.C.*
Medical Director, Food and Drug Administration, Department of Health, Education and Welfare

When the question is asked, "Aren't drugs safer now than they used to be?" the answer is very often heard, "Well, the ads say they are, and, besides, they have to be safe or they couldn't be on the market."

It is incumbent upon physicians who use these drugs to know that safety as employed here is a relative term based on certain conditions of use. To prescribe the newly developed drugs intelligently they should be aware of the methods used in developing the drug for the market and the means by which the [illegible] to be applied to any individual pharmaceutical.

There can be little doubt that the tremendous strides of the pharmaceutical industry in the United States over the past twenty years have resulted in the greatest development of new drugs ever experienced in any like period of recorded medical history. The fact that, of every 100 prescriptions written, 90 are for drugs that were not available even fifteen years ago is just one indication of the impact on medical practice that these developments have wrought. Only a very superficial knowledge of the economic picture of our country is necessary to understand that the gross sales of individual companies in the pharmaceutical industry have skyrocketed in these recent years with a corresponding rise in the value of their stocks. For the investors in these companies this growth has been an exciting and rewarding story, but beyond economic prosperity what else does this growth mean to the physicians, pharmacists, and to the rest of the population, many of whom within the next year will have to depend upon one of these new drugs for their well-being? It means even more new drugs will be available. Of the total income that accrues to the pharmaceutical industry, there is a substantial portion on which each year is designated for research. It is the boast of the pharmaceutical industry that the percentage of total sales returned to research and development is the highest in any field of business. As a result of their phenomenal growth, the amount of money that has been spent for research has increased year by year until it is estimated that, in 1960, the industry's

The New England
Journal of Medicine

Official Organ of
THE MASSACHUSETTS MEDICAL SOCIETY

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The other side of the picture, however, is that the more reputable drug houses have made great strides in raising their ethical standards, and have done invaluable work in devising and testing new drugs in their research departments. They can get high-grade investigators because they can pay better salaries than universities or noncommercial research institutes. Furthermore, so lucrative has the pharmaceutical industry become, and so enlightened, that it makes larger and larger grants-in-aid to nonprofit research projects. Thus, [illegible] to the industry. How good this is I cannot say, as I do not know, but I am strongly of the belief that if we don't know, but I am strongly of the belief that if it is necessary for medicine to work toward some form of ethical symbiosis with the pharmaceutical industry, if this can be done without compromising our own ethical standards. This is necessary because the industry can produce new scientific knowledge that medicine simply cannot afford to do without.

PATIENTS

And this brings us to a special subject that sharply [illegible] the difference between business and pro-

All the mass media also carry a steadily increasing volume of medical items, purportedly for purposes of public education. Some of these are excellent; some are dreadful. The great question is whether the total impact on the public of all this is good or bad. When it provides the stimulus that brings the patient to the doctor while his serious disease is still curable, it is good. When it leads to the pressurizing of doctors by patients to give treatment the doctor knows is not really indicated, it is bad. It has come to pass nowadays that patients, having soaked up some of the mass-media pronouncements, go to the doctor and tell him how to treat them. "Doc, I want a shot of penicillin." The doctor may know that this is neither needed nor desirable, but he also knows that if he doesn't give it, the patient will be off to another doctor who will. So the first doctor may give it even though it is not his best judgment. Actually, he is on a hot spot at his best judgment. Actually, he is on a hot spot. Of course in this case the ethics is clear enough. He should refuse to give it even though it means the loss of a patient. If he were not on fee-for-service there would be less of a problem.

The mass media can be very damaging also to the investigator. They will quote him out of context, give unwise emphasis to parts of his remarks, and let headline writers commit veritable mayhem on what he has said. "Great breakthrough in cancer just [illegible] all that sort of rubbish.

SPECIAL ARTICLE

PROFESSION OR BUSINESS?*

J. H. MEANS, M.D.†
BOSTON

MEDICINE, traditionally, has been considered to be a profession, even one of the so-called learned professions. Many definitions of profession can be found, but the idea common to them all appears to be that a profession is organized for service to humanity, whereas a business or trade is entered into for the sake of material profit. At first blush it might seem that there should be no confusion or overlapping between these, and I believe that until quite recently there has not been. The medical profession especially has valiantly put in writing its concepts of what constitutes proper professional behavior for the doctor of medicine. The late Willard L. Sperry, D.D., in his important little book entitled, "The Ethical Basis of Medical Practice," has this to say:

> Of all professional groups that of medicine has, on the whole, outlived its ethical errors [ignorance and malpractice] more successfully than has any other of the hundred professions. Lawyers and teachers have their codes of ethical practice, and in the latter [illegible] they are probably less dogmatic, and in the former instances more severe than in the case of medicine. As for my own profession, that of the ministry, unofficial codes of ethics are as numerous as the leaves of Vallombrosa, but they lack the authority of those other codes.

But as after Moses brought the Decalogue from God to man, lapses into the worship of Mammon came with increasing frequency, so also medical practice is presently slipping more and more from its high ethic into the behavior pattern of the market place. A neomedical writer within a few months has even had the temerity to bring out a book entitled, "The Doctor Business." It is no item that is causing some disputation among reviewers. I believe, therefore, that it is appropriate in the Guy Lecture this year to examine critically to what extent and in what direction deterioration is occurring in the boundary that should separate profession from business in the realm of medicine.

ETHICS

Let us begin with a look at some of the existing codes of ethics. The oldest and most famous is our

*The Guy W. Guy Lecture, delivered at Harvard Medical School, May 13, 1960.

†Jackson Professor of Clinical Medicine, Emeritus, Harvard Medical School; honorary physician, Massachusetts General Hospital.

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The Ohio Pharmacist is published at 40 South Third Street, Columbus, Ohio. Phone CA 1-5371.

Opinions that may be expressed in any signed articles in the Ohio Pharmacist are those of the author and do not necessarily reflect the viewpoint of the Ohio State Pharmaceutical Association on the subject.

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OHIO PHARMACIST

Schafer Answers Kefauver

To show the public the ridiculousness of the Kefauver sub-committee approach to drug pricing, the following news release was sent from the OSPA office to [illegible] newspapers, radio and television stations:

Eugene Schafer, North Canton, president of the Ohio State Pharmaceutical Association, has branded the Kefauver sub-committee investigations into drug prices as "political headline-hunting" on the part of the Tennessee senator.

"A careful examination of the hearings [illegible] States Schafer, thus charges made against the industry are completely unfounded. Charging manufacturers with high prices by comparing their costs of raw materials with their charge for the finished product is ludicrous.

"Let's take an example outside the drug field," said Schafer. "Corn sells for less than a penny and a half a pound, yet a pound of cornflakes costs us 44 cents. This is a 3500% markup, Kefauver would say. Or steel: Approximately 2.2 lbs. of steel is worth 11 cents at the mill. Yet .00054 of a gram of this steel in the form of a fine hairspring, vibrated into the workings of a good watch, is worth $10.25. Remembering that they are both steel, what is the markup? Using the good senator's system, the markup of the steel hairspring would be 1,725,590,900%. And just like a drug, if the watch is inaccurate, it is useless. But the inaccurate drug is not only useless — it is dangerous!

"Food costs have risen 4.9% since *1947-49*, while at the same time drug costs have been reduced 6.3%. Add to this the fact that most of today's wonder drugs — which are the most expensive — were unknown as recently as *10* years ago. Also, — *20* years ago the average U.S. wage-earner worked *1 hour and 41 minutes* to pay for an average prescription. Today we must work only *1 hour and 27 minutes* — and the drug really works.

"A few months ago government charges against five polio vaccine manufacturers for uniform prices on the vaccine made headlines. Just recently a Federal judge dismissed the charges as groundless. Thinking persons will do well to reserve judgement in the present round of politically-inspired hearings until both sides have had a chance to present their arguments, if this is allowed," concluded Schafer.

1960

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THE IOWA
Pharmacist
JANUARY, 1960
Vol. 14 No. 12

HERE'S WHAT GOES INTO THE PRICE OF A PRESCRIPTION

You give the pharmacist a piece of paper. A little while later, he hands you a package of medication. What you get for your money is not just a bottle of tablets or capsules or liquid. It's a great deal more. As follows:

Research

Thousands of man-hours and millions of dollars have been expended by the manufacturer to find the drug that will do exactly the job the doctor wants done. For every 20 drugs tested, at great expense, only one usually turns out right. Only after costly research . . . in the test tube, on animals, on human patients . . . is the product ready to go.

Production

To mass-produce today's wonder drugs . . . so that all who need them may have them . . . requires the most fantastically complex equipment. Moreover, complex and costly procedures must be followed to make sure that safety and potency and efficacy are guarded every step of the way — from raw materials to finished medication.

Availability

The finest drug in the world is useless if it's not available to the person who needs it — **when he needs it.** To deliver the newest drugs to every city and hamlet — overnight! — the drug industry maintains a highly organized distribution network.

Strategically located manufacturers' depots . . . wholesalers' warehouses . . . thousands of men and women and vehicles — all play a vital, indispensable role in getting every new life-saving drug into the nation's pharmacies in the shortest possible time.

Dispensing

To make sure he learns how to dispense your medication safely and accurately, the law requires your pharmacist to undergo 5 years or more of rigorous, costly education and training.

To do his job right, he must then invest thousands of dollars in stocking at least 3,000 different drugs, many of them rarely called for. He must also invest in a wide array of precision equipment — expensive equipment — designed for the proper storage, compounding and packaging of each prescription.

Those are **some** of the things you get when you pay for a prescription. But over and beyond all these, you also get better health . . . speedier recovery from illness . . . fewer hospital bills . . . and an ever longer life. They all add up to the undeniable fact that:

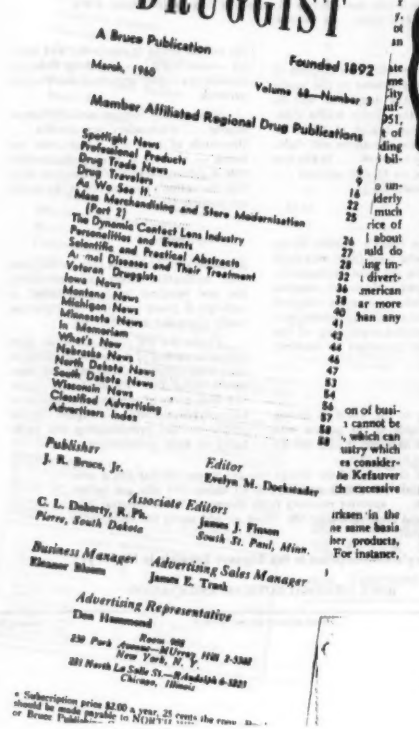
Today's Prescription is the Biggest Bargain in History! !

IOWA PHARMACEUTICAL ASSOCIATION

AS WE SEE IT

Inflation and Drug Prices

Regardless of whether the Kefauver Committee is ... of headline or publicity seekers, motivated ... is that the drug indus- ...



North Western
DRUGGIST

A Bruce Publication

Founded 1892

March, 1950

Volume 48—Number 3

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a cost of 18 cents for a loaf of bread made from 2¼-cent wheat would be equivalent to a 725% markup, a shirt made of 28-cent cotton and priced at $3.94 represents a 1,400% markup. Of course, any one can quickly recognize the profit distortion on items of which they have an understanding of what is involved in production and marketing, but the hidden costs in ... manufacturing ... are a mystery to them, so they accept the fantastic figures as normal.

The most portentous result of this gullibility is the impetus it gives to enactment of the Forand Bill or similar legislation, doubtless eventually ending in adoption of some sort of socialized medicine program.

Naively, the uninformed public believes that socialized medicine is free, quite forgetting that every government service must be paid for in taxes. In this case, instead of paying the pharmacist or doctor, the individual would pay the tax collector, whether they receive, or need, the service. Socialized medicine is free only for the indigent because they pay no taxes; nor do they need the service because they can get it anyway from welfare agencies.

Socialized medicine is both very costly and wasteful is evident by the annual outlay for this service. When it was inaugurated the annual cost was estimated at $500 million, but now it is in excess of $2 billion annually and provides very questionable care. Some patients are reported as waiting two years for a tonsillectomy; more serious surgery is frequently delayed much longer, due to overloading of the doctors, mainly because of malingering and other unnecessary services they must perform, but would not have to if the patient were paying for it directly. One of the most expensive items in the British budget nine-tenths of the cost of the medical care program is paid for by taxation.

* * *

Drug Samples

That too liberal distribution of drug samples to physicians is not only wasteful, but can actually constitute serious competition for retail pharmacy is plainly indicated by recent disclosure of resale operations in metropolitan cities.

One such organization—a mail order concern in Chicago—openly solicits drug samples from physicians for resale to druggists.

Any idea that the monetary returns are "peanuts" is refuted by recent bids from private trash collection companies for a contract to handle trash discarded by a medical center housing 300 doctors' offices in one of the largest cities in the country.

(Continued on Page 58)

The West Virginia Pharmacist

Vol. XIII, No. 1 January, 1960

Published monthly by the W. Va. State Pharmaceutical Association, P. O. Box 119, Oak Hill, W. Va. Subscription rates $3.00 per year or $.50 per copy.

Advertising rates furnished upon request.

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The Kefauver Hearings . . .

As a result of the Kefauver hearings on drug costs, many editorials have appeared in the newspapers in West Virginia. Most of these editorials never took the real facts into consideration. The "Morgantown Post" had an editorial which is worthy of your attention and for that reason, it is reprinted here.

DON'T FOOL US

A Senate Anti-Trust Subcommittee headed by Senator Kefauver of Tennessee heard testimony yesterday that a pharmaceutical manufacturer makes a pill for 1.6 cents, sells it wholesale at 17.9 cents, and suggests that the retailer sell it at 29.8 cents.

Looks pretty bad, doesn't it? Especially since the pill is said to be effective for those suffering from arthritis and asthma, many of whom may be short of cash to buy so expensive a medicine.

But there may be more to this than appears on the surface. How did the manufacturer know that this pill, derived from cortisone, is effective as an arthritis-asthma medicine? And once having made the discovery, what steps did the manufacturer have to take to establish that unknown side-effects would not be worse than the ailment sought to be cured or relieved?

Staff investigators of the Senate sub-committee said that their figures (which they obtained from the manufacturer) included the costs of preparing and bottling the pills, but not of marketing them. Apparently they did not include either the cost of the research which went into the development of this pill and the testing which had to be carried out before it could safely be put on the market.

And yet it must be a matter of common knowledge that research for new medicines can be very expensive. Look at the money being spent every year on innumerable research projects related to cancer, heart disease, and other intractable human ailments. It runs into the tens and hundreds of millions of dollars every year. Of course, most of this money is not being spent by the pharmaceutical industry; it is coming from public appropriations and from grants made by voluntary health organizations. This same thing was true of the Salk vaccine for polio. If the pharmaceutical industry had had to include in its price for Salk vaccine a charge for the development costs met by the National Foundation for Infantile Paralysis and other voluntary agencies the selling price might have been almost prohibitive.

Well, the best pharmaceutical companies have their own research departments which they support with their own funds. A good deal of what they spend on such research is money that goes down the drain. No researcher can be sure that he is going to come up with something useful. Much research, in fact, is certain to end in a blind alley, but may and often does have value by eliminating possibilities.

We do not know how much money the Schering Corporation spent in developing Meticortelone, the medicine mentioned in the Senate subcommittee testimony yesterday. But it surely must have spent something, and to eliminate that cost factor is unfair and misleading.

Then there is the matter of "marketing," which the Senate subcommittee's investigators specifically eliminated from their cost figures. Once a pharmaceutical company has developed and perfected a new medicine of proved efficacy, a demand does not immediately and spontaneously develop for that medicine. The manufacturer must make the medical profession aware of the development of this new medicine and must satisfy the profession that it can safely and effectively be used. This "marketing" process (if you want to call it that) can also cost quite a bit of money. The pharmaceutical companies have representatives called "detail men" who call upon physicians and furnish them information (and free samples). They must give evidence to back up their claims. It might well be that a pill costing only 1.6 cents would require an expenditure to bring it to the attention and acceptance of the physician who alone may prescribe it for their patients.

If the pharmaceutical industry is engaging in shady practices, the Senate subcommittee has a duty to bring those practices to the public's attention. But it also has a duty not to mislead the public and not to discourage the research from which the better treatment of human ailments can come.

(Reprinted from the Morgantown Post)

Rudy C. Hardman, formerly with Cohen Drug in South Charleston, is now located at Ft. Lauderdale, Florida. He extends any of his friends an invitation to visit him if they happen to be down that way. His address is 4772 N. W. 4th Street, Ft. Lauderdale, Fla.

Laurell A. Gainer has purchased the Corbett Drug Store in Romney and plans an enlarged prescription service by combining the Corbett prescription department with his own department. A centralized prescription department in his present store will be on one side of the street with the Rexall agency and other items directly across on the other side.

The Asclepians, pharmacy student wives organization at West Virginia University, held their Christmas party at the Medical Center on December 15. Mrs. John Miller presided at the business session, which was followed by a social hour with Mrs. Stamous Loucas and Mrs. Wilma Starkey as hostesses.

Missouri Pharmacist

Member State Pharmaceutical Editorial Association

CORA D. COX, *Editor and Business Manager* — JOHN HOSHOR, *Associate Editor*

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VOLUME XXXIV January, 1960 No. 1

PRESIDENT'S LETTER

Dear Members and Fellow Pharmacists:

The adverse publicity which has filled press, radio and television during the past few weeks as a result of the United States Senate Antitrust and Monopoly Subcommittee's investigation of Drug manufacturers' pricing policies, is being felt across the nation at the retail level. Too many customers believe some of the margins of the manufacturer which have come under sharp criticism apply at retail, and that we druggists are robbing the public on prescription medications.

Unfortunately the press has consistently failed to report the industry's explanation that the spread between manufacturer's cost and retail list covers such important and legitimate business expenses as research costs, advertising, distribution, and detailing. Presentations of the press have been almost exclusively based on sensational markup charges.

Whether or not the promise of the Senate Subcommittee Chairman, Estes Kefauver of Tennessee that inquiry will be made only of manufacturer's pricing policies is kept, the fact remains that to the public your store and mine represent the drug industry, and we have the problem of being faced with irate customers across our counters.

In other words the problem of explaining the present prices on the new wonder drugs to the public is ours whether we like it or not, and the less forthright we are, the more harmful the result.

The December issue of the Midwestern Druggist carries an article by H. W. Adkins which is highly revealing and is one which every drug store owner should study carefully and fully understand. As a matter of fact, I keep mine on display at my prescription department and have found it helpful in dealing with critical customers.

I also find that virtually every issue of every national drug publication contains material which can be used by us to combat the great injustice being done the retail druggists of the country by the implications resulting from this investigation.

It is not for me to attempt to tell anyone how you should meet this vexing problem. Each of you know your own business and your own best.

I do wish to stress however, the great importance to your business that you face up to the fact that we are not, at the moment, being regarded too highly as philanthropists by people in need of medication, and each of you must be prepared to explain and defend the price of any prescription or drug we quote.

Retail druggists across the nation could well be impaired by this probe, and the standing of pharmacy as a profession is at stake. The time is now to marshall our forces against the unjust criticism we are experiencing and which will most likely become more severe. The failure to do so could result in injuries which are irreparable. Each of us must do his share in his own way for the good name of all druggists and all pharmacy.

In connection I particularly like a quotation from Shakespeare which appeared in an article on this subject by Philip F. Jehle, N.A.R.D. Washington representative:

> Who steals my purse steals trash;
> tis nothing;—
> But he who filches from me
> my good name
> Robs me of that which enriches him not
> And makes me poor indeed.

Sincerely,

Virgil V. Phillips

VIRGIL V. PHILLIPS

Penna. Pharmaceutical Association

508 N. Third St., Harrisburg, Pa.
Phone CEdar 4-8151

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The Pennsylvania PHARMACIST
Official Journal of the PENNSYLVANIA PHARMACEUTICAL ASSOCIATION

Volume 41—Number Five December 1959

Dear Senator Kefauver:

Is 55c Too Much for a Year of Added Life?

. . . . so asked Mr. Louis Zahn, Chicago wholesaler. Below is the text of his letter to the Senator:

"Sen. Estes Kefauver
Chairman, Senate Antitrust Committee
Senate Office Building
Washington, D. C.

My dear Senator Kefauver:

Because I have spent a lifetime in the pharmaceutical business, I have been somewhat dismayed and concerned to read news reports about your forthcoming committee hearings on drug prices. All of these reports, and I hope that my assumption is mistaken, have indicated that the entire pharmacy profession is being considered guilty until they prove themselves innocent of imposing high drug prices upon the public. In this day when pharmacy is contributing so much to the well being not only of every American but of peoples throughout the world, it would seem to me that the pharmaceutical industry should be more subject to commendation rather than the kind of condemnation that seems to be coming from Washington even before your committee hearings commence.

I believe that the crucial issue to be considered by your committee is simple enough:

Is 10 years more of life worth 55 cents per year for prescriptions?

May I respectfully urge your committee hearings to consider this price tag that the average American pays for 10 years more of life than he had 30 years ago. Is a year of life worth 55 cents?

Certainly there is no one who would deny that this is the greatest bargain in the history of mankind. And yet, the very industry that has in large part helped to make this possible is being subjected to investigation that evidently accepts the implied guilt manifest in the [illegible] drug prices.

I should like to respectfully suggest that you weigh with the precise accuracy of a pharmacist all of the evidence in your hearings lest you damage the pharmaceutical profession and retard its remarkable progress of the last two decades.

Today's drugs [illegible] difference between aspirin and penicillin, between horse and buggy medicine and the most modern research techniques. To compare today's drugs and today's drug prices to 20 years ago is like comparing a horse-drawn surrey to today's automobiles and investigating why a modern car costs more than a horse and buggy. Today's drugs are entirely new products resulting from the research genius of America's pharmaceutical profession.

The cost to the average family of $22 a year more than prescriptions did 30 years ago is a remarkable achievement in bringing to the public what amounts to an amazing bargain. That the pharmaceutical profession has been able to accomplish this despite its tremendous costs in discovering so many new drugs is a miracle in merchandising no less than the miracle of the new wonder drugs themselves. If any spotlight is to be focused upon the industry, it should be to commend its farsighted executives as well as the neighborhood druggist rather than to harass them with investigation.

A lifetime spent in the pharmacy business impels me to plead with your committee to proceed with the utmost of caution and avoid castigating the retail pharmacist who represents the finest tradition in community service. Misdirection of your investigation to make the retail pharmacist an innocent victim by giving the impression to the public that his prices are excessive can set back pharmaceutical progress for years.

May I respectfully with the deepest sincerity implore your committee not to use investigative sensationalism in its hearings and not to handcuff an industry that has contributed more to the health and welfare of Americans than any other business.

Sincerely yours,
Louis Zahn"

Duquesne Students Hold Forum on Fair Trade

M. L. Miller and David A. Boyd, executive secretaries of the Pa. State and Allegheny Co. Pharmaceutical Associations, respectively, spoke as advocates of Fair Trade at a forum in Pittsburgh recently. The forum was sponsored by Duquesne University School of Pharmacy's student branch of the APhA.

Two economists, Dr. Arthur Sharron and Mr. James Cawley, were other members of the forum's panel, and spoke in opposition to Fair Trade. Mr. Crawley is a graduate student in the School of Business Administration, Duquesne University, and Dr. Sharron is an instructor in that school's Department of Economics.

Tom Wolfert, president of the pharmacy school's branch of the APhA, presided at the meeting. Moderator for the forum was Miss Patty Potesta, a senior in the Pharmacy School. Minutes of the preceding meeting were read by the secretary of the student organization, Miss Evelyn Kantoreszyk. Garrett Swenson was chairman of the program committee which planned the forum.

California Pharmacy
JOURNAL OF THE CALIFORNIA PHARMACEUTICAL ASSOCIATION
VOLUME 6 JANUARY, 1960 NUMBER 7

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"Big Brother" Kefauver . . . Starts Big Medicine Hunt

By JIM GENTRY

. . . One editorial on the subject of "Big Brother" Kefauver, the cousin [illegible], and his price [illegible] . . . appearing in the [illegible] is worthy of quote, "The most prevalent, the most dangerous and most prevalent mark-up in American life today is the political markup. What more like Estes Kefauver cost the taxpayer, compared to what the Kefauvers are worth to the taxpayers, would probably be much more than 7,079 per cent."

Columnist [illegible] writes in [illegible] Glen, California, newspaper, "Since the unfortunate furor over some individual drug manufacturer profits, reported in the committee of Senator Estes Kefauver, we have been doing what their committee might have done if they really wanted facts . . . we have talked to both drug manufacturer representatives and the drug outlets. In the course of it, we had a fine talk with Zigmund F. Kovalski, representing Eaton Laboratories of Norwich, New York; also, talked with Ed O'Rourke from the Family Pharmacy, and Irving Sprague from the Willow Glen Pharmacy. These people are local and have spent many years serving the public in what I would consider one of the most dedicated manners in current society.

Ed O'Rourke pointed out that the actual drug increase in the past ten years has been approximately 31%, compared with the approximately 65% increase in food. Taking one instance of many thousands as the criteria of 7,000% mark-up as they call it, is like naming Caryl Chessman the "All-American Boy." The average net profit for the normal to better drug store is probably less than 5% . . . and this takes years of training, capital, thousands of little requested drugs, precision work and a dedication to the better health of their community. . . . Of course, we do not condone the evident profiteering in isolated cases, but at the same time we wish to take into consideration the millions of dollars of drugs donated to hospitals and doctors . . . we consider the high costs of research and the many fantastic advances in the field of drugs. . . . These things did not happen by accident, and all who have been saved by the wonder-drugs owe at least consideration and a fair appraisal of the facts. On the other hand, the indirect implication of profiteering in the retail outlets could not possibly be further from the truth. Methinks the Senate Committee was looking for headlines, and the ever-duped press seems to fall for it every time."

So reports a Santa Clara County newspaper.

The Kefauver "investigative sensationalism" was not to touch the retail druggist . . . at least this was the Senator's promise when the hearings began.

Now, Senator Kefauver concedes retail drug prices will be involved in his drug price inquiry. Winnings as to the eventual victim of these inquiries have been sounded by the national and regional drug press.

Whether the recent FBI visits to the associations throughout California were to furnish data to Kefauver is not known. It is known that much of the FBI inquiry was directed by 850,000 year retainer attorneys (employed by the "new businessmen"). These same attorneys lost a civil suit last year in the same field. Now, the taxpayer helps in a similar inquiry; and the discounters ride into the Kefauver hearings.

The vehicle for the discounter ride was 75-year "young" Dr. Ethel Percy Andrus, president of the American Association of Retired Persons. Dr. Andrus testified about AARP's efforts to establish mail-order discount drug and prescription operations in Washington, D.C., and in California.

On notice from the state board of pharmacy, she said, the druggist serving her group in California had to stop on October 15th under a provision of the State's Business and Professions Code (B. & P. 651) prohibiting the holders of licenses to sell at a discount.

Dr. Andrus provided the subcommittee with a photostat of a letter from Dart Drug (Washington, D. C., discount drug operation) pointing to the suggested retail price, the cost to Dart, and its discount prices to Parke-Davis vitamins. Dart's prices were: 100's Abdol with minerals $2.38; 100's Abdec Capsules $2.08; 100's Myadec $4.99; and Paladec Pinta $2.96.

Dart's letter also offered Schering's Meticorten (prednisone) at $19.90 and noted that the manufacturer's suggested retail price was $29.85 for 100 5mg.

Dart immediately issued a press release regarding its generosity and attacked retail markups recommended by manufacturers as "unconscionable and thoroughly reprehensible." Dart president Herbert H. Haft was one of the prosecution witnesses in the criminal and civil antitrust cases against Parke, Davis & Company which the government lost. The civil case is now on appeal to the Supreme Court.

Consumers Information Bureau got into the act by issuing a "we love Dr. Andrus" news release and blasted fair trade and the NARD. This is the first time the consumer organization has appeared on the Washington scene. (They will be back with reinforcement according to reliable informants.) The press release gave no information about the organization except its mailing address, P. O. Box 493, Radio City Station, New York City.

If nothing else comes out of the "Big Brother" Investigations of Senator Kefauver . . . drug research will be curbed prematurely . . . fewer elderly people will live into the golden years . . . socialism will receive a push. . . BUT it is a good vote getter and Senator Kefauver must be running for reelection and needed publicity. Maybe someone will yet develop a medicine for political demagoguery.

THE NEW JERSEY
JOURNAL OF PHARMACY
OFFICIAL PUBLICATION OF THE NEW JERSEY PHARMACEUTICAL ASSOCIATION
Organized 1870 Incorporated February 18, 1874 Reincorporated June 23, 1915
VOLUME XXXIII MARCH, 1960 NUMBER 3

FROM
The Secretary's Desk
By JOHN J. DEBUS

CALM JUDGEMENT NEEDED

NOW, AS NEVER BEFORE, it is encumbent upon the community pharmacist to look beyond the four walls of his establishment and keep abreast of developments within the industry for whose products he is the final distributor to the consumer. Invariably it is the local pharmacist upon whom the consumer vents his spleen against misinterpreted injustices or to whom the consumer turns for valid information regarding the many allegations now being leveled at the industry. The manner in which the local pharmacist handles himself during these critical days could possibly determine whether or not private initiative in the pharmaceutical industry will be destroyed and whether or not we will be brought under a system of regimented state medicine.

It is highly imperative to keep alert to what is going on. Senator Kefauver, leader of the current agitation, is less interested in learning the truth about the pharmaceutical industry than he is in creating headlines that portray him as the shining hero. By some strange quirk of circumstances he has been able to enlist in his crusade public opinion moulders who for reasons known only to themselves help him in misrepresenting [illegible]

[illegible] point is the article in the February 15th issue of LIFE magazine which is inconsistent to the extent of being utterly ridiculous. It blatantly states that the $2 billion spent by the American public last year for prescription drugs was too high a price to pay without revealing the fact that the per capita cost was less than $11 which is considerably less than the per capita expenditures for cigarettes, alcoholic beverages or amusements. It criticized the high cost of promoting the sale of prescription drugs with the statement that such promotion is not directed at consumers.

In a subsequent statement they say that such promotion efforts encourage patients (consumers) to want the drugs thus promoted. The article states that the promotion efforts are directed at 158,000 physicians and that "in a single day a doctor may collect $40 worth of free drug samples." My calculations show that this would amount to about $1.9 billion dollars worth of free drugs received by physicians per year. However, LIFE winds up its tirade by accusing physicians of being in good part responsible for the high cost to consumers of prescriptions by falling for the brand name promotions leveled at them by the industry and sugests that physicians can save money for chronic invalids by personally ordering drugs for them from doctor's supply houses. LIFE ignores the fact (if it is a fact) that the $1.9 billion dollars worth of drugs furnished free to physicians would just about cover the entire cost to the public of prescription drugs.

The foregoing emphasizes the need for exercising calm judgement in evaluating and interpreting the publicity leveled against pharmacy and the drug industry today. Almost without exception those who criticize us do not know the facts as we know them. We must take the time to assemble the facts and present them to the public in their proper light.

HUDSON VITAMINS SEIZED

F.D.A. seized $650 thousand worth of vitamins from Hudson Vitamin Company for misbranding claims made in their catalogue. The mail order vitamin company retained possession of the seized vitamins after it had agreed to destroy the 75,000 offending catalogues.

This is the company that makes a play for patronage by telling the public that all vitamins must meet strict government regulations without directing attention to the fact that such strict government regulations involves jurisdiction over false advertising claims. It was making false claims in their catalogue advertising that caused their products to be confiscated.

The New Jersey Journal of Pharmacy

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DECEMBER, 1959

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NEW YORK STATE PHARMACIST

Official Publication of The Pharmaceutical Society of the State of New York

DAVID FROLICH
Editor

EXECUTIVE SECRETARY'S PAGE

On The Firing Line

Kefauver's investigations into drug prices are putting the New York State pharmacists on the firing line.

Your customers will be coming to you with their doubts and beefs and this is your opportunity to show your profes[illegible] but not by ducking the [illegible] throwing the blame on the manufac[illegible] you strongly to face the matter squarely, for the facts are on our side.

Medical and pharmaceutical discoveries of the past two decades have added ten years to the life span of people in this country. During that time, nine-tenths of all drugs now prescribed by doctors were introduced by the pharmaceutical companies of America.

According to Dr. Austin Smith, a physician who [illegible] Pharmaceutical Manufacturers Association, the Labor Department's wholesale price index for drugs, pharmaceuticals and cosmetics has actually declined in the past decade, while the retail price index for Rx drugs has lagged behind the figure for all retail items. This year, industry will spend about $194 million on drug research alone, a five-f[illegible] increase in ten years. Last year, pharmaceutical firms worked with 14,600 different chemical substances. Of these only 1900 showed enough promise for clinical testing, and less than 40 are likely to become prescription drugs.

As pharmacists, we should realize that once the distorted Committee charges are exposed to the truth they will crumble for the falsehoods they are. For example, when the facts were in on the so-called 1,118% markup on prednisolone, it was found that committee investigators had not included the company's production, selling, research, administrative, royalty and wholesale discount costs:—the "exorbitant" profit turned out to be a "reasonable" 12.3%.

Interestingly, I have observed that while the distortions were making the headlines, the real important news was buried in the newspapers' back pages. Officials of the Arthritis and Rheumatism Foundation (See story on page 8) deplored the sad fact that millions of arthritis-sufferers are "victimized by unscrupulous arthritis quacks" who advertise and market "worthless nostrums." They urged that manufacturers be required to prove the effectiveness of non-prescription drugs or devices before they can be allowed to market them.

I am proud to say that I have always fought against the quacks who prey on the public health. Our voice against fraudulent and misleading advertisements was one of the first raised in the industry. I have also fought against the sale of drugs by individuals woefully unqualified to protect and acquaint the public with the facts.

Through the years, I have actively opposed the Proprietary Association's (and its allies among the supermarket interests) efforts to break down the Pharmacy Laws.

Through the years, your organization has actively kept prescription prices down by battling the commercial interests trying to drive legitimate drug items into the supermarkets. How little the public realizes that the profit made on these conventional over-the-counter items has kept Rx prices as low as they are.

Through the years, I have taken a forthright stand against the few immoral and dishonest operators who lure the public with price-bait and then gouge them on blind items or vitally needed prescriptions.

Through the years, I have striven to protect the health needs of the indigent. Presently I am contending with Welfare authorities that these patients are entitled to the very best medicine available, and not cheap equivalents and/or questionable substitutes.

When your customer wants to know the facts behind the investigation, tell him the whole story. It will do him good and will give you a lift too.

Nicholas S. Gesualdo

VOL. LXXIX JANUARY, 1960 NO. 1

A Message From Your President

COMBAT ADVERSE PHARMACY PUBLICITY!

In a committee room of the Senate Office Building in Washington, D. C., December 7, Senator Estes Kefauver of Tennessee rapped his gavel and called for order. Thus began the Congressional hearings on "administered drug prices," certain to put the nation's drug stores in a glare of publicity such as they have probably never before been subjected.

Though the committee has indicated the investigation will deal only with pricing policies at the manufacturers level . . . and that we retail pharmacists "have no reason to fear the hearing will affect us adversely," once a Congressional hearing gets started in the free swinging way that characterizes such probes, everyone in [illegible] to be [illegible] publicity, much of it likely to be unfavorable.

We may find ourselves, along with everyone else in the industry, among those at whom charges of wrong doing are leveled by the press, and the public, if not actually by the committee itself. The fact is, for every branch of the drug industry, from the smallest retail pharmacy to the largest manufacturing house, the hearings mean a severe ordeal, a trial by newspaper headline, by innuendo, and half truths.

We should each ask ourselves, "How will I combat this adverse publicity to my profession and livelihood?" First explain to your customers when handing them a package of medication what they get for their money. It is not just a bottle of tablets or capsules or liquids, but a great deal more—the benefit from costly pharmacy research; production; fast distribution and safe, accurate dispensing.

The Rx purchaser obtains benefit from thousands of manhours and millions of dollars expended by the manufacturer in this research, and from the mass production of today's "wonder drugs," requiring tedious procedures with costly, complex equipment. By paying for a prescription, they also get drug availability, for a drug is useless, if not available when needed. To assure this does not happen, an organized distribution network is maintained to deliver the newest drugs to any city, overnight.

Insuring safety and accuracy in the compounding of a prescription, a pharmacist is now required by law to complete 5 or more years of education and training before he can dispense. Then he must stock at least 3 thousand varied drugs and expensive, precision equipment to practice pharmacy. Above and beyond all this, an Rx customer gets better health, speedier recovery from illness, fewer hospital bills, and an even longer life!

Not only is there a need to apprise your customer of these facts, but community leaders must be enlightened with the reason today's drugs are the biggest bargain in history. This can be accomplished by arranging an annual pharmacy program in each business, service or civic club in your community. To aid you, the TPA Film and Speech Library is always available, carefully stocked with a selected array of visual and speech material that will forcefully tell the story.

Therefore, I call upon each of you, from every segment of Texas pharmacy, to stage at least one pharmacy program for 1960 in your community as your New Year's Resolution!

W. B. Bums

Lee Baker, brother of Dee Baker, Past-President of the Association, who now lives in Texas, sent us the following editorial from the Southern Pharmaceutical Journal by the Editor, Walter Cousins, Jr., This is a sample of the sentiments that are being expressed by the Drug Press of the Nation that we have had the opportunity of seeing.

DEMAGOGUERY AND DRUGS

"Two things have become crystal clear in the recent hearings on drug prices-the forcesdetermined to install socialized medicine in America have found a new sounding board, and politicians havegathered in an opportunity for political capital. Both groups-and their interests may be intermingled-seized upon the fact that everybody has health of one kind or another, and made capital of the human instinct against the cost of everything.

At the outset, it ought to be said that the drug business should have no fear of congressional investigations under honorable terms because the record of humanitarian service traced from the research laboratory, through manufacturing, distribution and patient-use has never been equalled in the history of man. The drug industry can stand on that record-even cost-wise in any inquiry by people of open mind.

That the hearings were rigged-in this day of rather universal rigging-became painfully apparent in the early days of the hearings when the Sub-Committee's Chairman complained of the length of a statement a pharmaceutical executive desired to make after the public press had had its hey-day of mouthing the Sub-Committee's charge of more than 7,000 per cent profit. Both sides should bat in any ball game.

The Sub-Committee's witnesses chose to carefully mount their testimony in connection with profits without taking into consideration any costs beyond raw material. Every intelligent American knows that the raw material in any product is probably the least cost-determining the material, fabricating and packaging a product, selling and delivering it, guaranteeing its efficacy and availability, add their necessary costs, and, what should be important to [illegible] provide jobs and opportunities, revenue and [illegible].

As a result of the intelligent presentations made by the management men of America's great pharmaceutical laboratories before the Sub-Committee, the Chairman diverted to the strange attack of showing that these companies offer their products to government under the prices charged in free enterprise, and wanted to know why. If there ever was a fundamental fumble in the whole proceedings, this must have been it.

The Sub-Committee knows now that the pharmaceutical manufacturer earns about sixteen cents out of every dollar he receives, turning eight cents over to the same government that supports the sort of circus that the investigation represents. This leaves eight cents out of sales dollars to provide for further research in behalf of the nation's health, to go into surplus for less successful days, and to pay stockholders for the use of the tools that their investment provided. The public, however, may not know these facts, because they have not been given them, and they have no burning desire to understand them.

Out of all this, the deep impression that comes from the hearings is that the pharmaceutical participants-manufacturer, wholesaler, pharmacist and physician-have done a poor job in their public relations. In spite of the magnificent accomplishments of the health team, the man in the street is unsympathic.

Every individual in the production and distribution of drugs who fails to confront his public with the facts about medicine, 1960 model, falls into demogoguery as severe as that evidenced by the do-gooders in government."

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The Maryland Pharmacist

MARYLAND PHARMACEUTICAL ASSOCIATION

Office of Publication: 650 W. Lombard Street, Baltimore-1, Md.

SAratoga 7-0746

Entered as second class matter December 10, 1925, at the Postoffice at Baltimore, Maryland, under the Act of March 3, 1879.

VOLUME XXXV **DECEMBER, 1959** **No. 3**

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PRESIDENT'S MESSAGE

Fellow Pharmacists:

Because of the proceedings issue of the "Maryland Pharmacist", I have not had the opportunity to address any remarks to you for several months. When you read this, I am sure the Holiday Season will be completed, and it is my hope that it was a very pleasant one, both in your personal life, and in your business.

Now for business—With the advent of the Kefauver investigation into the ethical drug field, it is my opinion that Pharmacy faces the greatest challenge of its career. I am not putting "Fair Trade" in the background because Fair Trade is your financial livelihood, but a federal investigation is a challenge to our integrity as professional men. It is true that as I am writing this, the investigation has only been into the manufacturing procedures, but I am sure this will continue down the line to the retailer. Please bear in mind that while at times we personally dislike some practices of the manufacturer, this is not the time to "air" our differences.

Remember the manufacturer is one of our industry, and although we may have differences of opinion, it has been his research products and know-how that has promoted Pharmacy financially to what I know think is its greatest peak. Defend the manufac[illegible]ally, and I think we w[illegible] one of m[illegible] wrote "first rigged TV, then payola, and now y[illegible] know who."

When the investigation reaches the retail level, don't apologize [illegible] high prices and standards, defend them. Certainly the average person must rea[illegible] his life expectancy has been extended more than ten years in the last decade. Could this have been done without the high cost of research, the finding and then discarding of thousands of products because of toxicity or antiquity? Can any of us forget the millions of doses of Influenza Vaccine that were destroye[illegible] and equipment made obsolete, with the advent of the Sulfas?

[illegible] someone can put a value on a year of life, maybe we [illegible] concede the high cost of drugs; till then, defend and fight for your professional position!

Sincerely,

GORDON A. MOUAT
President

WHAT IS YOUR WORKING TIME WORTH?

You can figure it out for yourself from the following chart, courtesy of the Dictaphone Corporation.

If you Earn	Every Hour Is Worth	Every Minute Is Worth	In One Year An Hour a Day is Worth
$ 5,000	$ 2.56	$ .04	$ 625
10,000	5.12	0.9	1,249
15,000	7.68	.13	1,874
20,000	10.25	.17	2,501
25,000	12.81	.21	3,126
50,000	25.62	.43	6,251
100,000	51.23	.85	12,500

AMERICAN
JOURNAL OF PHARMACY
AND THE SCIENCES SUPPORTING PUBLIC HEALTH
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EDITORIAL

DRUG RESEARCH TODAY

THE large number of new medicinals released during 1959 is evidence of the almost feverish activity in drug research. Such research is spurred on to an ever-increasing tempo by the intense competition between the many companies comprising the drug industry.

Critics of the drug industry who claim that there is no competition today would soon change their opinion if they could observe the almost frenetic lives of research executives who know full well that company position and even survival depends on new and better drugs, and these quickly.

Other critics voice their displeasure that not all of the new drugs released each year are major breakthroughs as were drugs like penicillin, cortisone, and chlorothiazide. To expect such major accomplishments from each program of drug research is completely unrealistic. Furthermore, the improvement of some already existing drug by a therapeutic margin of say ten to twenty per cent may spell the difference between success and failure in treating many patients. Is there anyone, for example, who considers cortisone as good as prednisone or the latter in turn as good as dexamethasone? Should we have ceased all sulfonamide research with the development of sulfapyridine or sulfathiazole? It must be remembered that in setting up a research program no one has, or can have, the assurance of a ringing success. A project even after long and costly pursuit may result in something with only possible superiority. Even this often cannot be established for a certainty until it has been used on thousands of patients in an objective clinical appraisal. Only too often, early clinical enthusiasm gives way to the sad conclusion that the new drug is not quite what was hoped. These are the risks that must be taken and the costs that must be written off—costs which are often staggering.

The question frequently arises whether the industry, the health professions, and the public at large are benefited by the present head-

February, 1960

long pace of pharmaceutical research, much of it unrewarding. Those who say that the achievements do not justify the expense and that the resulting multiplication of products is wasteful fail to understand certain basic facts concerning research and the free enterprise system. In the first place, just who is there in industry, in government, or elsewhere who could predict just what research should be undertaken and invariably be right? As the situation now exists, many capable men match wits on this with the certain knowledge that good judgment and lots of luck will [illegible]. Those who believe in some other system just do not believe in free enterprise, which is the system in which Americans profess to believe.

Secondly, just where in the world can our critics point to a better, more productive system? Russia? England? Where, other than in America and some few countries whose economic system is patterned after our own, are today's miracle drugs more widely available, the professions free, and the health of the people given greater care and attention? Those who would tamper with our free and smoothly functioning system of drug research and distribution should reflect on what the inevitable result of such tampering would be. Some of our critics seem as naive as a child who is surprised that the clock he has "fixed" won't run. Others, we suspect, subscribe to the philosophy of Marx and Lenin but hide it behind a facade of alleged concern for the people. Thinking Americans should not be misled by such phony liberalism. We have much that needs correcting in this country if we are to survive. Let us not tamper with one of our towers of strength for which we are known and respected the world over. As it has been so aptly stated elsewhere, "There is no missile-gap in the drug industry." Neither will there be as long as private initiative and freedom from unreasonable restraint continues as our national policy toward the industry.

L. F. Tice

A national publication devoted entirely to professional Pharmacy and pharmaceutical service. It is sent exclusively to a selected list of the country's leading prescription pharmacists and hospital pharmacists and pharmaceutical executives.

It aims to interpret and record accurately the most significant and interesting advances and events in the fields of Pharmacy, Medicine, and the sciences allied to Public Health.

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Notify publisher promptly of change of address. Subscription rates on request. Member of the A. P. A.

Postmaster: If undelivered please notify The American Professional Pharmacist, 1647 Northern Boulevard, Manhasset, N. Y.

American Professional Pharmacist

VOLUME 26
NO. 1
JANUARY, 1960

the challenge to Pharmacy of the Kefauver hearings

More than 50¢ cents of every dollar spent by the public for prescription medication goes to the prescription pharmacist and the wholesale druggist. This is a fact accepted by everyone in our profession and industry. It is an unquestioned economic certainty. Yet this should bring home to each and every retail and hospital pharmacist the throat which the intent and temper of the hearings of the Senate Subcommittee on Antitrust and Monopoly hold for everyone in Pharmacy, not merely for the beleaguered manufacturer.

It is alleged that the Subcommittee's militant chairman Sen. Kefauver (D.-Tenn.) in the interests of preserving peace among his constituents at home in an election year, has given assurance that retail drug prices and distribution costs will not be considered at this time by his investigative group. However, we have already had ample warning to the contrary, as Subcommittee member Sen. Dirksen (R.-Ill.) and fellow-member Sen. Smathers (D.-Fla.) both have clearly indicated their intentions to delve into this area.

Pharmacist-readers of this issue of the AMERICAN PROFESSIONAL PHARMACIST must appreciate the special significance which we place on this challenge. The Kefauver hearings are a serious threat to *all* of Pharmacy. Do not lightly brush aside a problem that will become more serious as time passes. It is not merely the concern of the industry at large or of the individual companies who are the present targets. Do not selfishly take pleasure in their present discomfiture. You will hear more about it from your own [illegible] seeking ashcans *as you*. What harms *any part of* Pharmacy harms *all* of Pharmacy. The calculated headline-seeking attack of politically-inspired investigators may soon be digging into such subjects as professional fees, retail mark-ups and direct discounts, super-market and discount store dispensing, and the economy of old-age mail-order prescriptions!

VOL. LXXXII, No. 4
February 13, 1960

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Editorial Comments

Kefauver Ignores the Essentials of Fairplay

SENATOR Kefauver deserves volumes of [illegible] for the manner in which he has conducted the investigation directed on prices charged for medication. He must know that it is wrong to resort to unfounded allegations. Or does he? The evidence is abundant that he seems unable to discern the elements of jingoism. Furthermore, he [illegible] of fair-

Senator Kefauver made it clear that he is of the mind to harass witnesses with opinions and facts that conflict with the preconceived notions of the probe staff. He trusts with gentle hands the witnesses selected (and in some cases subpoenaed) to reinforce the defender, or maintains to be correct

staff (in particular, Dr. John Blair, economist, and Paul Rand Dixon, attorney) employ insinuations and revised figures and outrageous tabulations to "convict" the large drug firms. The investigation to date has been a trial instead of a search for information. Senator Kefauver and the probe staff have revealed that they care nothing about the injustices they perpetrate or the injury they cause through abuses of authority and arrogant contempt for the essentials of fairplay.

Here is an example of publicized statements that emanate from the investigation. It was said that 50 tablets of Miltown (200 mg.) sell for 40¢ in Argentina and $4.65 in the United States.

How about the facts?

The peso has been devalued in Argentina and hence it is awkward to compare prices in Argentina with prices in the United States. Comparison on the same basis is used for prices on Miltown in Argentina and the United States would place the cost of bread to the consumer at 2¢ a loaf and a pound of high grade beef steak at about 25¢ in Argentina.

Conclusion of Information

Another error in the publicized statement on the prices of Miltown in Argentina and the United States was the omission of the information that Miltown sold in Argentina is in powder form and that it is produced in Italy where the cost of production and distribution is much less than it is the United States. These facts were not mentioned.

Senator Kefauver continues to stress that drug prices deprive indigents of needed medicines. He seems to think it is the sole obligation of the pharmaceutical manufacturers to solve the deplorable situation. He bypasses the obvious realities as he strives to smear the large drug firms. Senator Kefauver ignores the plight of the elderly caught in the isolation of inflation. Many of them exist on meager fixed incomes which have ceased to provide the barest of necessities and he helped to bring about the misery they suffer. He voted for spendthrift measures that contributed to the downgrading in the value of the dollar. Senator Kefauver weeps crocodile tears for the people forced to endure the agonies of poverty right here in America.

1958 Net Income of Five Leading Industries

Industry	Number of Companies	Net Profit as a Percent of Sales
Mining (other than metals & coal)	8	19.5%
Cement	30	16.1
Telephone and Telegraph	33	13.8
Electric and Gas Utilities	246	13.4
Drugs and Medicines	27	11.4

The table shows that industries outside the drug field make higher net profits as a percent of sales than the pharmaceutical manufacturers. The First National City Bank of New York provided the information for the table. The reader will note the "take" of the public utilities in comparison with the drug firms. The table answers unfounded allegations of Senator Estes Kefauver, chairman of the Senate Antitrust and Monopoly Subcommittee, that the pharmaceutical manufacturers gouge the people.

Journal of the **AMERICAN PHARMACEUTICAL ASSOCIATION**
Practical Pharmacy Edition

This Journal is the official monthly publication of the American Pharmaceutical Association, dedicated to the elevation and application of the profession of Pharmacy through communication of authoritative, scientific, professional, and cultural information. It is devoted to the education of pharmaceutical practitioners, and it functions as the professional voice of Pharmacy, which is directed to all members of the profession of Pharmacy in education, government, industry, and professional practice.

VOL. 21 NO. 4 APRIL, 1960

Senate minority leader Everett McKinley Dirksen has had a long career of public service. First elected to Congress in 1932, he served eight consecutive terms. In 1950 he was elected to the U.S. Senate and is now in his second term as senator from Illinois. A member of the judiciary, labor and public welfare committees of the Senate and of the joint committee in relation of nonessential federal expenditures, Dirksen also serves on the Republican Policy Committee. The Illinois senator was responsible for inserted in the Congressional Record, March 7, 1960, of an article on mail-order prescription schemes. A graduate of the University of Minnesota law school and a first world war veteran, Dirksen is a member of many organizations including the American Bar Association, the American Legion, Elks, Masons, and Veterans of Foreign Wars.

a message from Senator Dirksen . . .

The Honorable J. Warren Lansdowne
Chairman, House of Delegates
American Pharmaceutical Association

Dear Mr. Lansdowne:

I wish it were possible to appear before the House of Delegates conference on March 27 or 28, but unfortunately the press of Senate business makes it impossible for me to accept the gracious invitation.

I am glad, however, that Mr. Peter N. Chumbris, counsel to the minority of the Senate antitrust and monopoly subcommittee, will appear, and I am confident he will bring you an interesting and timely message.

I regard the drug industry as dynamic in its every aspect, and it has made an astonishing contribution to the health and well-being of our country. It is so important that the profit incentive be maintained because its end result will be greater research, better drugs and an even more constructive contribution to the national welfare.

Because of the importance of the industry to the economy of the country I have sought at all times to make certain that misleading exhibits, statements and impressions were corrected because they do a disservice to an industry in which dedicated men and women are laboring earnestly to improve national health.

I trust your conference will be at once fruitful and constructive.

Sincerely,

Everett McKinley Dirksen, *Illinois*
United States Senate Minority Leader

Presented at the APhA House of Delegates interim meeting in Washington, D.C., March 28.

It is needless to point out the great importance of the pharmaceutical profession and industry, be it drug manufacturers, wholesale druggists, retail druggists or those servicing hospitals and institutions. The testimony before the United States Senate antitrust and monopoly subcommittee hearings on drug pricing policies is replete with the tremendous benefits derived in the United States and throughout the world by the dynamic efforts and vision of the pharmaceutical profession and industry. It is therefore incumbent upon all pharmacists to guarantee and protect such a reputation from within as well as from without.

Congressional investigations and hearings have become a significant part of the legislative machinery of our Congress so that vital facts and various views may be brought to the attention of Congress on pending legislation or legislation that needs to be enacted into law. The jurisdiction of congressional investigations and hearings has been tested in the federal courts. Usually the courts are reluctant to pass judgment on the methods used by congressional committees but the Supreme Court in its decision in the so-called Watkins case provides a wise guide to the legislative branch in establishing areas appropriate for investigations. The Court held that an investigation could not be a fishing expedition and that the private affairs of individual citizens could not be exposed to public view simply for the sake of exposure.

On January 22 Senator Everett McKinley Dirksen (Illinois) ranking Republican on the antitrust subcommittee and minority leader of the Senate, commented on some of the misleading exhibits and statements made by the staff during the drug hearings. With his comments he included editorials from 30 newspapers from all sections of the country, critical of some

Dr. SMITH. These montages indicate the comments that have appeared on behalf of the industry, and of its support of the sick people during the past few weeks and months.

One of the charts that was presented at the last session had to do with concentration and competition in the industry. To this, I would like to direct myself for a few moments in response to your invitation.

There are several small charts over there ——

Senator KEFAUVER. To the extent that we can get them into the record.

Dr. SMITH. These will take only a moment, but I believe they are important, Mr. Chairman, for the record.

Senator KEFAUVER. Dr. Smith, the first one will be——

Dr. SMITH. I will only draw your attention to this fact, because there is a supplementary mimeographed statement which will be presented to you for the record. This is offered as comment on charts, 18, 19, and 20—it was decided after viewing all the errors concerning discoveries and concentration in Dr. Blair's charts last February that it would be impossible and too time-consuming to offer detail for the subcommittee. Hence these explanatory charts for your information, and in addition for the record, a report, which is mimeographed. This and the charts reveal the true situation for concentration.

On the left—just a word of comment——

Senator KEFAUVER. The next is 263. We will mark them as we go along.

(Exhibit No. 263 appears on p. 10825.)

Dr. SMITH. On the left is the chart that reflects the presentation made earlier by Dr. Blair. We have extended this chart to indicate the actual competition that in sales, exists in this country. The part on the right—there is a dividing line between—was missing in the original chart. We believe that this, when it is examined in the record, will clearly demonstrate, along with our mimeographed statement, that there is competition in sales.

The next chart, the one showing the colored bars, also indicates the competition that exists, in this case in one special field—the corticosterioid field. It has been said there is no competition or limited competition——

Senator KEFAUVER. That will be made exhibit 264.

(Exhibit No. 264 appears on p. 10826.)

(The mimeographed statement referred to, exhibit 283, may be found on p. 10831.)

Dr. SMITH. This, we believe, proves otherwise.

The next chart, which is concerned with the ataractics, the tranquilizers, proves our contention that there is free competition in this field—as you can see from the various drugs that are used for the various diseases, ranking from allergic disorders, to senility symptoms on the right.

Senator KEFAUVER. We will make that exhibit 265.

(Exhibit 265 appears on p. 10827.)

Exhibit 263

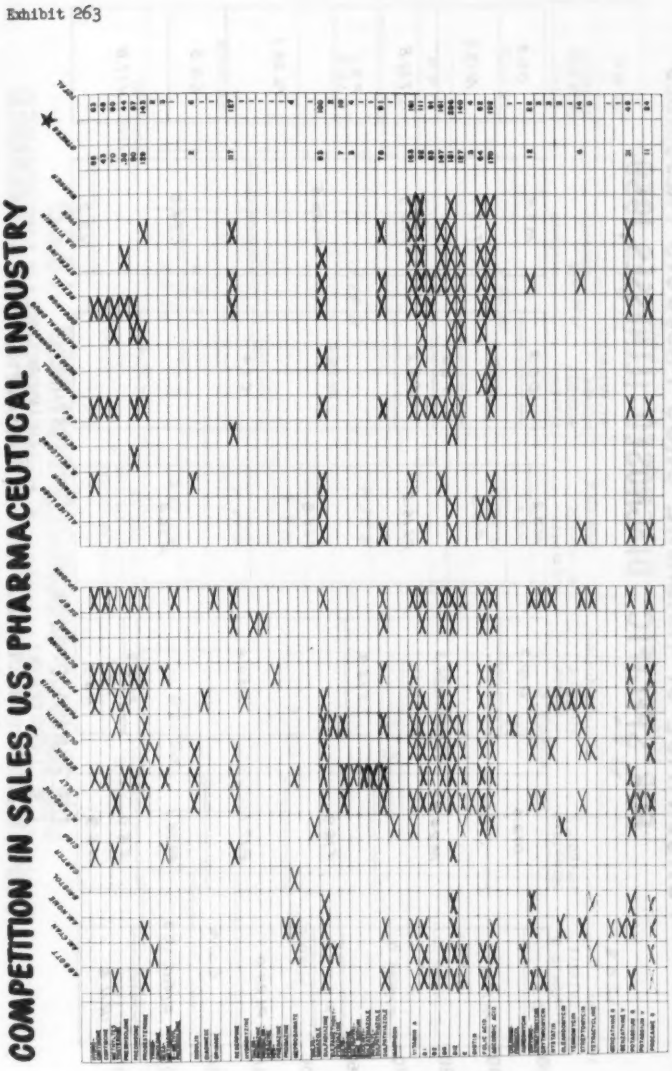

COMPETITION IN SALES, U.S. PHARMACEUTICAL INDUSTRY
SOURCES: AMERICAN DRUGGIST, BLUE BOOK, 1959-60
ANTIBIOTICS DATA IN FEDERAL, 1960
★ ESTIMATED NUMBER OF ADDITIONAL COMPANIES SELLING ABOVE PHARMACEUTICAL PREPARATIONS.
BASED ON CONCENTRATION CURVE, 1958, INTRODUCED AT ANTITRUST HEARINGS, 26 COMPANIES, 21 PHARMACEUTICAL PREPARATIONS.
ASSOCIATED BY THE ADDITION OF 14 OTHER COMPANIES SELLING ABOVE PREPARATIONS.

EXHIBIT 264

PERCENTAGE OF HORMONE DRUG PRODUCTS PRESCRIBED FOR SPECIFIC DIAGNOSED ILLNESSES, 1959

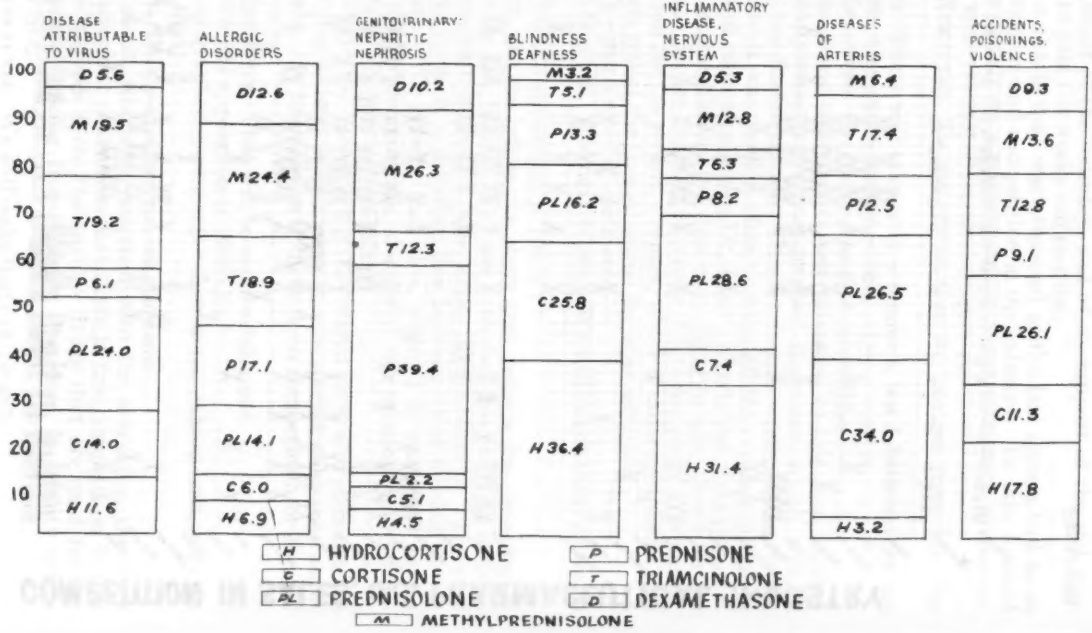
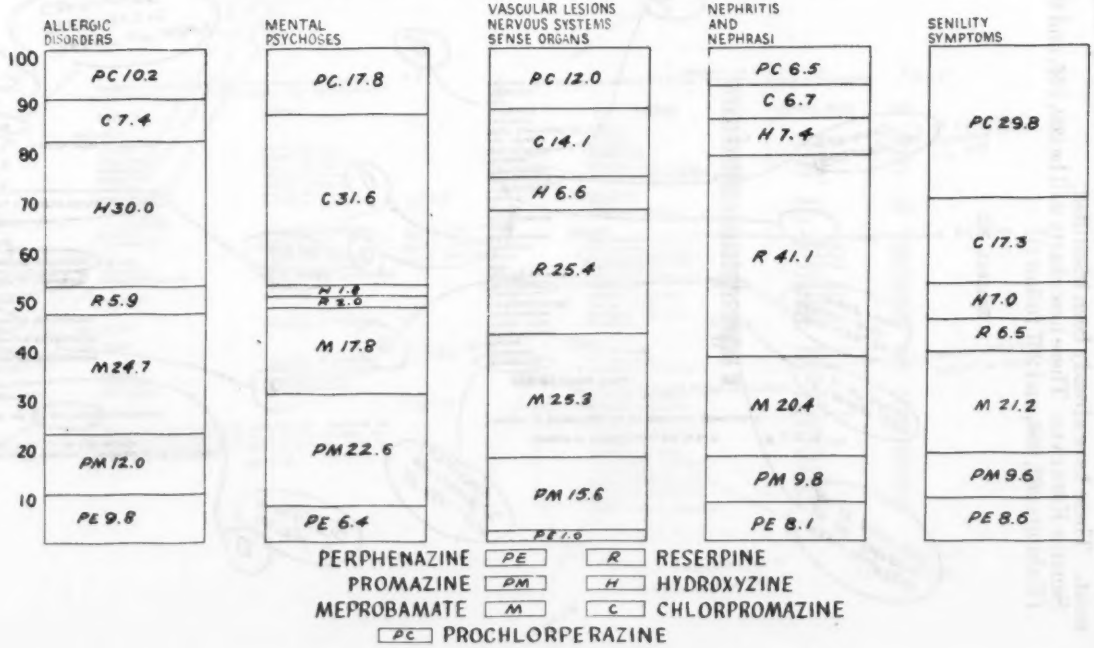


EXHIBIT 265

EXHIBIT 265

PERCENTAGE OF ATARACTIC DRUG PRODUCTS PRESCRIBED FOR SPECIFIC DIAGNOSED ILLNESSES, 1959



Dr. SMITH. The next three charts concern discovery and devolopment. These have already been identified.

Senator KEFAUVER. These new charts will be 262, 266, and 267.

(Exhibits 262, 266, and 267 follow:)

Exhibit 262

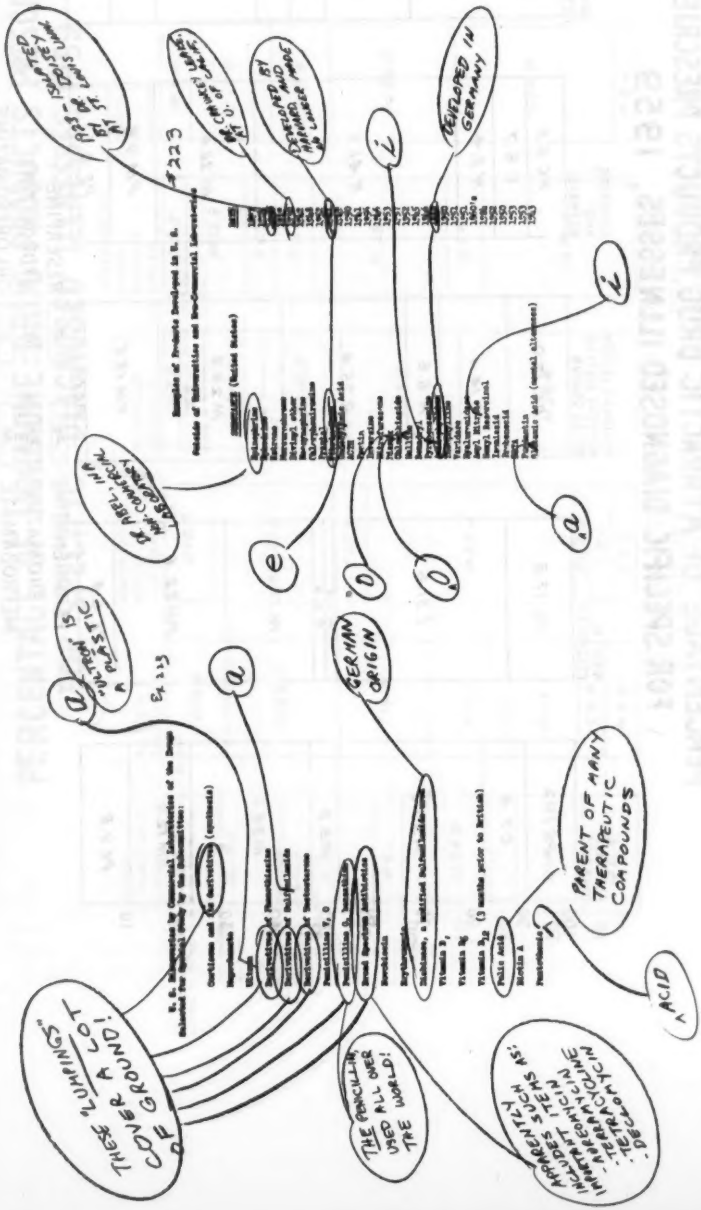

DISCOVERED IN U.S.A.
DISCOVERED BY BRITISH AND DEVELOPED IN U.S.A.
DEVELOPED IN GERMANY
GERMAN ORIGIN
PARENT OF MANY THERAPEUTIC COMPOUNDS
THESE "FINDINGS" COVER A LOT OF GROUND!
THE PENICILLIN USED ALL OVER THE WORLD!
AMERICAN STEPS AS: ANTIBIOTICS
ACID

Exhibit 266

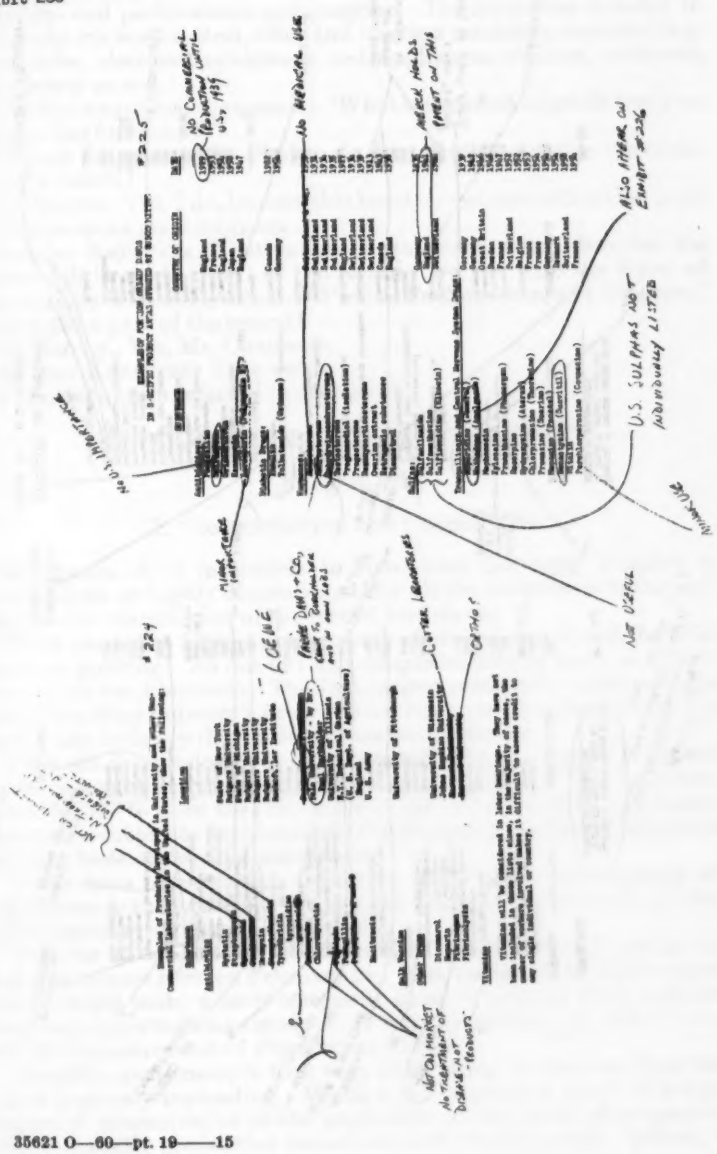
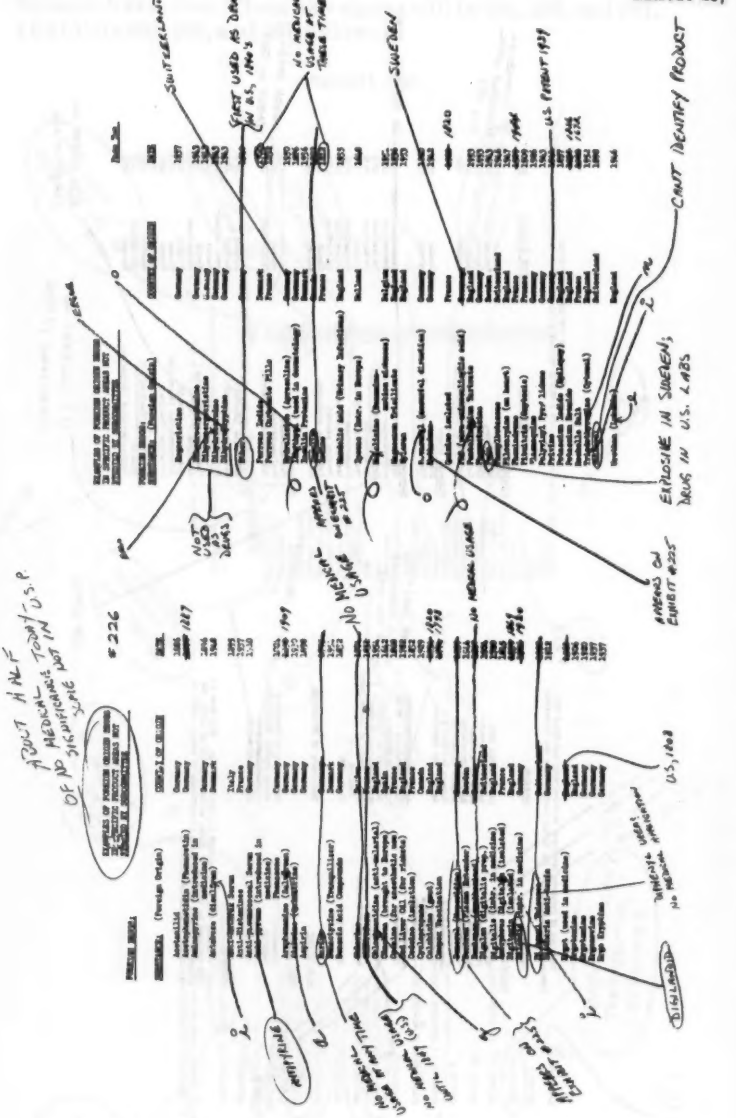


Exhibit 267


ABOUT ½ NOT OF NO MEDICAL SIGNIFICANCE TODAY IN U.S.A.
#226
SWITZERLAND
FIRST USED IN U.S.A. IN 1944
NO MEDICAL USAGE AT THESE TIMES
SWEDEN
U.S. PRODUCT
CAN'T IDENTIFY PRODUCT
ERGOTAMINE IN SWEDEN; DRUG IN U.S. LABS
NOT USED AS DRUG
NO MEDICAL USAGE
U.S., 1948
DISCONTINUED

Dr. SMITH. In addition, for the record, we would like to introduce this brief statement, which refers to a digest of a study by A.T. & T., on profits and performance and progress. The industries included in this study are textile, steel, office and business machines, meatpacking, retail sales, electrical equipment and appliances, airlines, railroads, and electric power.

The study explored the question "What is the effect of profit levels on business performance?"

Senator KEFAUVER. Dr. Smith, do you want to put this statement into the record?

Dr. SMITH. Yes, I do, because this bears on our contention that good profits promote good business.

Senator KEFAUVER. Your prepared statement which describes the charts will be made a part of the record. Do you wish the digest of the study by A.T. & T., entitled "Profits, Performance, and Progress," to be made a part of the record?

Dr. SMITH. Yes, Mr. Chairman.

Senator KEFAUVER. Very well.

(The statements referred to follow:)

STATEMENTS BY DR. AUSTIN SMITH

EXHIBIT 283

I. CONCENTRATION AND COMPETITION

Gentlemen, it is impossible to show that the drug industry is monopolistic or highly concentrated, for all the evidence is to the contrary, as an examination of the record here shows.

There are about 1,300 manufacturers of ethical drugs, and the total has been growing. No one of these companies does as much as 10 percent of the total business. The four largest companies together share less of the drug industry's gross volume than you have found to be the case in any industry this subcommittee has examined.

That the drug industry is characterized by ease of entry is proved by the constantly growing number of manufacturers. You have been given figures to show that the share of market enjoyed by any manufacturer is subject to rapid shifts. The degree of product obsolescence is prima facie evidence of competition.

These facts prove a high degree of competition and disprove all arguments to the contrary. No one can challenge these facts, and the subcommittee itself hasn't even tried.

Now, let us consider an exhibit entered into the record during my last appearance here, on February 24. You were kind enough to agree that I could make a later statement about it because there had not been any opportunity to study it. I refer to exhibit 233, which is entitled "Concentration of Production, 1958."

Frankly, gentlemen, it took very little study to discover that this chart is grossly misleading. While it is presented as proof of a high degree of concentration in the production of important pharmaceuticals, it actually proves that there is no such concentration. Indeed, it can be extended to prove that there is an unusually high degree of competition.

It should come as no surprise to this committee or to the American people to learn that a particular medication within a broad category of drugs is manufactured in bulk only by the company that patented it. It is not monopolistic for a car manufacturer to control the production of his make of car, or a soapmaker his detergent. Nor is it monopolistic for a drug manufacturer to control the production of a drug he has developed at great cost to compete with other drugs.

However, if you look at the chart carefully, you find that only 27 of the 51 products listed are manufactured in bulk solely by single developers. The other 24 are manufactured by two, three, or more bulk producers. The so-called concentration of production, therefore, is far less than any reasonable person might expect it to be.

This is not the only misleading aspect of the so-called concentration chart. Perhaps even more significant is its failure to indicate that within each of the seven categories the drugs are highly competitive. To show fully how competitive they are, I have had some charts prepared for your inspection.

This chart demonstrates that practicing physicians do not use a single corticosteroid drug in the treatment of a given disease, but rather that they may use any one or a number of steroids in the treatment of a specified disease or indication for a given patient. Each color on this chart represents one of the seven corticosteroids listed on Dr. Blair's concentration exhibit. Each vertical bar represents a condition for the cure or alleviation of which steroids are often prescribed.

This certainly demonstrates that the seven corticosteroids, no matter who manufactures them, are competing for the same markets. I might add that the percentages shown on this chart are estimates of national use, based on the known volume of prescriptions reported last year by a weighted sample of physicians.

(The chart referred to, exhibit 264, may be found on p. 10826.)

This is a similar chart breaking down the usage of tranquilizers mentioned in Dr. Blair's compilation. Notice again that no one kind of tranquilizer is used exclusively in the treatment of any single disease. Doctors feel free to prescribe for an individual patient the precise medication that suits his particular needs, choosing from among a number of drugs in this category. Obviously, since this is the case, the producers of any one kind of tranquilizer know that they are competing with the producers of every other kind. This is why it is utterly wrong to imply that because a producer controls one tranquilizer he has a monopoly. He has no more of a monopoly on the tranquilizer market than the producer of a single kind of automobile has on the automobile market.

(The chart referred to, exhibit 265, may be found on p. 10827.)

What you have seen in these charts are only a few typical instances drawn at random to illustrate the irrefutable fact of intensive competition within the drug industry among the producers of therapeutic chemicals.

But this is only a segment of the pharmaceutical industry, and the products selected for inclusion in the so-called concentration chart are only basic therapeutic chemicals. In actual fact neither the committee's chart nor those I have just shown you give any real understanding of the breadth and intensity of competition that characterizes

the manufacture and sale of finished pharmaceutical products, the prescription medicines that we all have occasion to use, in contrast with bulk pharmaceutical chemicals.

You cannot assume that, because one or two or three companies account for all the bulk production of a particular product, they also control the market for the drug. That is far from the truth. There are about 1,300 companies manufacturing and selling prescription drug products.

In only a relatively few instances does a single company maintain control over a product from bulk production to finished pharmaceutical package, as you can see from this chart. Listed down the left side are all the drugs mentioned in exhibit 233. Opposite each drug are indicated the companies that produce the bulk chemical, certain other major competitive companies, and also the number of additional but unnamed companies that produce and sell the product in finished dosage forms.

(The chart referred to, exhibit 263, may be found on p. 10825.)

By way of illustration, let us look at a corticosteroid hormone, prednisolone. Dr. Blair's chart would have you believe that three companies control the market for this important drug. Actually the standard references used by physicians and druggists show that this market is shared, not by 3 manufacturers, but by 43.

And prednisolone is but one of seven corticosteroids on the committee chart which are competing with one another. You will notice that this is the rule for all these drugs, rather than the exception.

These charts and statistics prove beyond any doubt that the drug industry is one that has long embraced the concept of "total competition."

In the drug industry, as we have seen, competition begins with research, the scientific pursuit of new or improved drugs. This competition is largely responsible for the remarkable parade of effective lifesaving products that have transformed medicine in our lifetime.

Out of the competition in research evolve the basic new products, such as the 51 listed in exhibit 233, which are only a part of the new drugs that have come on the market in the past dozen years or so. New products compete with older products and, if they are better, they replace them. To the extent that the therapeutic values of new drugs overlap, they compete also with each other.

Finally, there is keen competition at the wholesale and retail levels, where brand competes not only with brand but with generic products, using all the methods of competition common to other businesses. In fact, this competition is so keen that the drug industry has been severely criticized in this chamber for its very vigor. Witnesses and others have claimed the industry is guilty of competitive excesses—in advertising, direct mail, sampling, and other sales methods.

It seems to me that in their zeal to find fault with the drug industry some of our detractors are trying to have their cake and eat it, too. The drug industry cannot be both too highly concentrated and also too competitive, for these are mutually exclusive concepts. Where the one exists the other is absent. You cannot conclude that this is a highly competitive monopolistic industry.

I have tried to give you the facts about total competition in the drug industry, gentlemen, and to illustrate them with statistics. These facts and statistics are worth more study than we have had time to give them today. I urge your further attention to them so that you cannot be misled by such incompleted and distorted presentations as exhibit 233.

Now to conclude this short presentation on concentration and competition I want to read a brief review I have prepared of an important study dealing with pertinent facts.

DIGEST OF A STUDY BY A.T. & T. ENTITLED "PROFIT, PERFORMANCE, AND PROGRESS"

A study of regulated and nonregulated industry, May 1959

The industries included in this study are: Textile, steel, office, and business machines, meat packing, retail sales, electrical equipment and appliances, airlines, railroads, and electric power.

The study explored the question "What is the effect of profit levels on business performance?" It revealed that profit is one of the three elements vital to American progress. The other two are good management and a good product. Without all three no business can contribute much to the economy. According to this report a good profit enables a business to do research and develop new or better products, to build more plant facilities and make more products, to invest in more efficient plant facilities, to provide more and better jobs as it grows, and thus to furnish the product at lower cost to the consumer than if profits were small. In other words, "a good profit enables a business to help improve the living standards of America. A business with poor profits cannot do this."

The report revealed the erroneous nature of the early concept of economists that competition must be thought of in terms of price alone. Today total competition as practiced by successful firms takes in price, service, quality, and innovation. The study suggests that firms failing to compete on all these fronts fall behind.

The criteria of business performance in this study were growth, more and better capital equipment, more capital investment, more and better products for the money, research and innovation, more jobs and better pay, and good citizenship and social conscience. Included in the latter criterion were: location, design, and upkeep of plants so they contribute to good living in the community; participation by employees and management, as good citizens, in government, education, and civil affairs; activity and leadership in groups that work for the good of the community; and assistance—both personal and financial—to charitable drives, hospital building funds, and private colleges and universities.

An interesting aspect of this report brings out the fallacy of the concept that regulation keeps prices low by restricting profits. Actually, experience of both competitive and regulated companies indicates that good profits come from a good product, good management, and low costs—not high prices.

So, among the conclusions reached in the report were these:

Profit and performance are inseparable. * * * In every industry, good performance has come from companies with good profits. * * * In fact, a firm's ability to perform well is directly dependent on its profit level. * * * By every criterion profitable companies have been able to serve the Nation better than poor companies. Profits are vital to growth, more and better capital equipment, more capital investment, more and better products for the money, research, and innovation, more jobs and better pay, and good citizenship.

The industry studies show—

that research, innovation, and new products are the lifeblood of successful competitive companies. But in regulated industry there are few examples of real basic research. Most regulated firms expect their suppliers in the competitive world to do the research in connection with the equipment and materials they buy.

EXHIBIT 284

II. DISCOVERY AND DEVELOPMENT

I am grateful for your willingness that I comment on some of the exhibits entered into the hearings during my earlier appearances before you. Among those which require comment are exhibits 223–226, which are lists comparing the drug discoveries and developments in this country with those abroad. These lists attempt to document a line of thought expressed a number of times before this subcommittee by witnesses seemingly hostile to the pharmaceutical industry.

Before considering these exhibits, however, we might say a word about witnesses. The drug industry employs more advanced scientists in relation to its size than any other industry. And yet you have heard only a few former industry employes and only a few from the academic ranks of medicine.

May I suggest you also hear from the many who believe they are making important contributions to America by working for the drug industry; who work with the industry in important research posts in academic circles, and who are recognized as outstanding clinicians. Why does this subcommittee not hear from a dozen or even a hundred scientists, now happily employed, and get a truly representative point of view?

Frankly I am shocked by two aspects of the attack on American research. Tabular material inserted into the record and similar oral testimony taken is shocking, first, because of seeming attempts to belittle the quality and value of research by the United States in comparison with other countries. And I speak not only of research carried out in the laboratories of industry but also of research in the laboratories of universities, hospitals, Government and other nonprofit institutions.

As an example, let us consider the lists submitted as exhibits 223–226. Even a cursory examination of these exhibits discloses the distortion and misuse of figures that have been resorted to in an effort to discredit American achievements and to overrate the considerable achievements of our friends overseas. Yet even the subcommittee's own compilation—erroneous as it is—proves beyond doubt that American drug industry research has led the world in the past two decades.

Exhibits 223 and 224, for example, tabulate 48 drug products credited to U.S. companies and 20 credited to noncommercial U.S. labora-

tories. Exhibits 225 and 226, on the other hand, total up 110 "examples" of drugs originated in other countries. The comparative length of the lists alone creates the impression that the U.S. leadership in drug research is a myth. This so-called documentation has been supported in testimony since received by this subcommittee.

A study of these compilations, however, brings out quite another story. For it is evident that, in order to compile the list of oversea achievements, somebody had to search medical history for centuries. Two drugs on the foreign lists date back to the 1500's; 2 to the 1600's; 6 to the 1700's, and 19 to the 1800's.

More than half of all the foreign items cited date back before 1939, when the U.S. drug industry was just pioneering modern chemotherapy.

A comparison of American drug progress which has been great only in the last 20 years, when stacked up against all the rest of the world for a period reaching back centuries before the American Revolution, is regarded by some as intended for only one purpose—to discredit the very real achievements that have transferred leadership in medical research from Europe to this country in the past generation. As a U.S. citizen I consider this unbecoming, to say the least, of anyone whose security and comfort—yes, even luxuries—stem from the United States of America.

The second shocking aspect of the materials presented as factual data to this subcommittee (and to the public) are the errors, the inconsistencies, the vagueness and the distortions contained in them. I intend to report fully on them.

Brushing the misrepresentation aside and accepting the lists at face value, what do we find?

We find that a fair examination of this information, incomplete and misleading as it is, shows that since 1939 the U.S. pharmaceutical industry has been far and away the research leader of the world.

If you compare the drugs credited to American commercial laboratories alone since 1939 with the drugs credited to all the rest of the world in that period you get an entirely different picture from that intended. You find that the U.S. pharmaceutical houses have originated or first developed at least 35 of the listed products in contrast to Germany's 14, Switzerland's 7, and France's 5. No other country on these lists is responsible for as many as four new drug products during the era of modern chemotherapy.

I must say that it is not my intention to disparage the excellent work that is being done overseas. We are indebted to many countries for some of the greatest advances in medicine, and we are proud to acknowledge that debt. I know of no executive in the U.S. pharmaceutical industry who does not maintain a lively interest in bringing the best possible medicines to the American people, no matter where these medicines may be discovered. On the other hand, I know that everywhere in the world scientists also acknowledge that American drug industry research is leading the way toward healthier and longer lives for all the peoples of the world.

Now I'd like to return briefly to the exhibits we have been discussing to explain why I said earlier that they contain serious errors, inconsistencies, vagueness, and distortions.

(The charts referred to may be found beginning on p. 10943.)

I think you have a right to know how incompetent these exhibits are. For that purpose we have prepared these charts, which simply reproduce the pages of the exhibits and point out some of the errors contained in them. I will quote to you from an analysis we have had made of these exhibits.

CRITICISMS OF THE KEFAUVER SUBCOMMITTEE'S EXHIBITS ON UNITED STATES VERSUS FOREIGN DRUG DEVELOPMENT (EXHIBITS 223–226)

Sometimes the best practical demonstration of the defects in a distorted and misleading exhibit is the preparation of a new one. Since the Kefauver subcommittee's exhibits on United States versus foreign drug development are misleading, we have attempted to correct some of their fallacies by preparing the attached single chart. The major faults we have attempted to overcome are outlined below together with the mehods we have adopted.

I

Though the products in the Kefauver lists are called "examples," there appears to be no consistent basis for their selection. There is thus no meaning to the fact that the table for foreign origin drugs contains more products than are credited to all American sources, commercial and noncommercial combined. As a matter of fact, all the drugs mentioned for pharmaceutical laboratories (exhibit 223) are actually in use today, while those listed for "university and other noncommercial laboratories in the United States" (exhibit 224) include several antibiotics which either are not now or never were on the market for human use.[1] Giving these noncommercial antibiotics in exhibit 224 is particularly misleading since such important pharmaceutical industry contributions as Aureomycin, Terramycin, Tetracycline and Declomycin are not listed separately, but presumably lumped under "broad spectrum antibiotics" on page 3053.

Only about half of those in the "foreign origin" compilation (exhibit 226) have any significance in American medicine today, a number having been deleted from the U.S. Pharmacopaeia. In addition the tabulations are very uneven. To list practically every known alkaloid of ergot or digitalis, but also to note the general terms "antihistamines" and "benzoic acid compounds" (exhibit 226) is analogous to listing the individual manufacturer of every variety of spice in a supermarket and then citing Noah's cow as the source of all the dairy products. There is no obvious criterion for selection in this list, and though it claims to cover areas not studied by the subcommittee, it includes insulin and benactyzine also on the list of foreign origin drugs covered by the subcommittee (exhibit 225). It also includes "barium" and "chlorine" which are not drugs at all.

To overcome these defects, we have prepared lists of products in the specific areas listed by the subcommittee (anti-infectives—including antibiotics and sulfonamides, diabetic drugs, sex hormones and corticosteroids, and tranquilizers and central nervous system drugs) and have added to them cardiovascular-renal drugs, antihistaminics, anticholinergics, enzymes, and antineoplastic agents. For reasons of expedience, we have excluded diagnostic agents, general anesthetics, biologicals, gastrointestinal agents and hormones other than those specifically listed, anticoagulants, radioactive isotopes, and vitamins, hematinics and nutrients. These areas were given least attention by the subcommittee. Although the American pharmaceutical industry has made some dramatic contributions in them, such as the development of vitamin B_{12} and folic acid and the Salk and flu vaccines, the pattern is probably little different than for the product areas included. In the categories used, we have taken only drugs of importance in therapeutics today, as determined by 1959 sales volume. We have endeavored to cover all types of disease treated by drugs in the groups included, so that medicinals of fairly low sales volume may be listed if they are the most important ones for the treatment of a less prevalent type of disease. By including only those drugs in active use today, we have omitted some predecessors of great historical significance (such as Cortone and Aureomycin, major discoveries of the American drug industry, and sulfanilamide, of European origin). But if less

[1] Polymyxins A and D (polymyxin B is used); filipin [sic]; streptothricin; totomycin; candicidin and synnematin B.

or none of the predecessor is being sold at present, it is a safe assumption that the improvements represented in its successor are so important a to be recognized independently. One may be sure that a drug enjoys a high sales volume only because American doctors have found from repeated observation that it provides the best therapy in a given situation.

II

The word "develop" in exhibits 223 and 224 is misleading, because the "developers" listed are often only the "discoverers." Though streptomycin was found at Rutgers by Professor Waksman while he was working under a grant from Merck, the antibiotic would never have reached the market had it not been for extensive development work done by Merck, Squibb, and other laboratories. Similarly, the discoverers of nystatin, Drs. Elizabeth L. Hazen and Rachel Brown, have written: "The staff of the Squibb Institute has overcome what appeared to be insurmountable difficulties due mainly to the insolubility and instability of nystatin. The credit for the achievement of the marketable product known as Mycostatin is due to the farsightedness, persistence, and talent of the large staff concerned with the product." [3] In the process of developing a drug for general use, innumerable problems must be solved—discovering methods of determining the purity and efficacy simply but incontrovertibly so that each new batch may be assayed to insure uniformity; converting a test-tube synthesis into a large-scale process; masking unpleasant odors or tastes to make the compound palatable; and many more. For each new preparation the problems are different.

To give credit where credit is due, we have listed both the discoverer and the developer of each drug included. It would be impossible to express the importance of the development work for each individual product without giving the actual amount of money expended. For most of the enzymes, prednisone, and many others, their present significance was probably not foreseen by the person who discovered or isolated them. In most cases, extensive laboratory work was necessary to make the drug marketable. On the other hand, where our best evidence suggests that most of the development work done by an American company was in clinical trials rather than in research work, we have so indicated by adding a "(C)" for "clinical" after the developer's name.

III

It is difficult to understand the use made of dates in Mr. Kefauver's tables. In the case of ether, the date given is that of the original discovery of the compound, long before it had been demonstrated in the 1840's to be capable of use in anesthetizing human beings and before Dr. Squibb had purified and standardized it to the point where it could be administered with a reasonable prediction of the result.

Though many other dates vary by several years from those we have been able to verify, it is sometimes difficult to place a discovery exactly. It is surprising, however, to see arsphenamine (Salvarsan—misspelled as Salversan) dated 1850, when standard sources credit Ehrlich with discovering it in 1909.

To be consistent as to the dates used, we have taken the "Year of Introduction," which wherever possible has been obtained from New and Nonofficial Drugs, 1960.

IV

There is a fallacy in the subcommittee's repeated implication that any change in such complex molecules as phenothiazine or the steroid nucleus is a "slight molecular modification" requiring no inspiration or acuity to synthesize or characterize pharmacologically. This is something like saying "Eve is a slight

[3] New York State Department of Health. Annual Report of the Division of Laboratories and Research (Albany, 1955), pp. 25–26.

molecular modification of Adam," or that the male hormone, testosterone, is a molecular modification of the female hormone, progesterone. These things are true but any reasonably well-informed person is aware of the difference in activities of both examples. In practice there are an infinite number of possible ways to vary substitutions on such nuclei as steroids or phenothiazines and a wide variety of different—even directly opposite—pharmacological actions can result. It may take thousands of dollars in the laboratory to find and prove the utility of a "slight molecular modification."

We have endeavored in our list to characterize the significance of each drug included. Sometimes little differences will be found in the statements for two or more drugs, though they are different chemically. That two different drugs with very similar actions are both able to maintain high sales volumes is, we think, a healthy sign of competition and gives the doctor an extra chance for effective treatment of a patient who may become resistant to one of them.

v

We have endeavored to avoid the multiplicity of typographical errors in the Kefauver list.[3] In a few cases we could not even be sure what product was intended.[4] Though mistakes are understandable, such a high proportion of them makes one wonder whether there was a real desire to secure accurate information.

Though numbers have little relationship to the importance of individual contributions, a summary of the attached list may be interesting. Of the 94 drugs listed, 44 were discovered in the U.S. commercial laboratories, 7 in U.S. noncommercial laboratories, and 43 elsewhere. For the 70 drugs introduced since January 1, 1950, 37 were found in U.S. commercial and 4 in U.S. noncommercial organizations, and 29 were of foreign origin. Surely this record of initial discovery, together with the even greater expenditure of time and money for development, is one for which the American pharmaceutical industry may be commended.

(The attached list referred to begins on the next page.)

Frankly, gentlemen, I find it incredible that such material can be seriously presented to a subcommittee of the U.S. Senate as straightforward fact which you are expected to use in determining whether an industry is properly observing the antitrust and monopoly statutes.

To set the record straight, therefore, I ask you to accept and mark as an exhibit this analysis of exhibits 223–226 and the accompanying tabulation which contains pertinent and correct information about the discoverer and developer of various important drugs in use throughout the world today.

One final word on this subject: Those critics who try to disparage the U.S. drug industry by saying many modern drugs have been brought here from abroad miss the point. Of course the American industry is quick to bring foreign discoveries to this country for the benefit of our people. This is done in the public interest, openly. Nobody claims America has a monopoly on scientific savvy.

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[3] Corrections we have noted are as follows: p. 3052: undecycleic acid; chlorothiazide; Pyribenzamine; amyl nitrite; Furadantin; p. 3053: Ultran; sulfanilamide; pantothenic acid; p. 3055: gramicidin; *flipin*; p. 3059: disulfiram; antipyrine; Salvarsan; chlorguanidine; Digilanid; p. 3060; *dihydroergocornine*; dihydroergocryptine; IcAthyol; meclizine; pentolinium; triiodothyronine.

[4] Phenindrone and Thicoyol, p. 3060.

IMPORTANT DRUGS IN CURRENT USE IN SPECIFIED FIELDS

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ANTI-INFECTIVES					
Antibiotics, General					
potassium penicillin G, penicillin tablets USP	Pentids and many others	1945	Oxford U., England	Squibb	First orally effective penicillin preparation
streptomycin USP	numerous preparations	1946	Rutgers U., under grant from MSD	MSD, Squibb	First antituberculous antibiotic; revolutionized the treatment of tuberculosis
chloramphenicol USP	Chloromycetin	1949	Yale U., under P-D grant	P-D	The first agent effective for treatment of typhus and typhoid fever; useful against many other infections
oxytetracycline USP	Terramycin	1950	Pfizer	Pfizer	One of the early broad-spectrum antibiotics, active against gram-negative and gram-positive bacteria, some large viruses, the rickettsiae, etc.
benzathine penicillin G USP	Bicillin	1951	Wyeth	Wyeth	A new, sparingly soluble repository penicillin which produces protracted blood levels and thus has enabled worldwide "one shot" therapy for syphilis and non-venereal treponematoses
erythromycin USP	Ilotycin, Erythrocin	1952	Lilly	Lilly	Alternate for penicillin particularly in penicillin sensitivity or resistance; also for intestinal amebiasis

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ANTI-INFECTIVES					
Antibiotics, General (Contd)					
tetracycline USP	Achromycin, Tetracyn, Polycycline, Steclin, Panmycin	1954	Lederle, Pfizer	Lederle, Pfizer, Bristol	An improved broad-spectrum antibiotic, with fewer side effects than previous ones
phenoxymethyl penicillin	V-Cillin, Pen-Vee	1955	Lilly	Lilly	More potent for oral medication than any penicillin heretofore available
demethylchlortetracycline	Declomycin	1959	Lederle	Lederle	A basic modification of tetracycline structure that provides greater antibiotic potency through slow degradation and consequent stability in body fluids, as well as reduced clearance rate, which produces prolonged antibacterial levels
Antibiotics, Antifungal					
nystatin	Mycostatin	1954	N.Y. State Dept. of Health	Squibb	The first safe and effective antifungal for topical and oral treatment of moniliasis, which is often a sequel to broad-spectrum antibiotic therapy
griseofulvin	Fulvicin; Grifulvin	1959	ICI, England	Schering (C) McNeil (C)	Oral antifungal antibiotic for the treatment of ringworm
Chemotherapeutics					
sulfisoxazole USP	Gantrisin	1949	Roche, U.S.A.	Roche, U.S.A.	A more potent and safer urinary antibacterial than heretofore available

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
			ANTI-INFECTIVES Chemotherapeutics (Contd)		
isoniazid USP	Rimifon	1952	Roche, U.S.A., Squibb	Squibb, Roche, USA.	Important advance in treatment of tuberculosis; patients often may remain ambulatory; mortality drastically reduced
nitrofurantoin	Furadantin	1953	Eaton	Eaton	Broad-spectrum drug for oral treatment of bacterial infections of the urinary tract
sulfamethoxy-pyridazine	Kynex	1957	Lederle	Lederle	New compound with high antibacterial activity, solubility and absorption, and long duration of activity
sulfadimethoxine	Madribon	1958	Österreichische Stickstoff., Austria	Roche, U.S.A.	Upper respiratory and urinary antibacterial with therapeutic effectiveness at low dosage, low incidence of side effects, and more prolonged blood levels than other antibiotics
			ANTIDIABETICS		
insulin (plain) USP	Iletin and many others	1923	Toronto U., Canada	Lilly	Since insulin has been available diabetics have been able to lead a virtually normal life
protamine zinc insulin USP	numerous products	1937	Steno Hosp., Denmark	Lilly, Mulford, Squibb	Insulin compound which reaches its maximum effect in 12-24 hours instead of 2-3 with unmodified insulin

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ANTIDIABETICS (Contd)					
isophane insulin USP	NPH Iletin	1950	Steno Hosp., Denmark	Lilly	Because of its timing effect isophane insulin simplifies and improves the management of the average case of diabetes
tolbutamide	Orinase	1957	Hoechst, Germany	UpJohn (C)	First American oral antidiabetic, effective in a majority of adult patients
phenformin	DBI	1959	U.S. Vitamin Corp.	U.S. Vitamin Corp.	Oral antidiabetic effective in patients resistant to other oral antidiabetics
chlorpropamide	Diabinese	1959	Lilly	Pfizer	Oral antidiabetic with 2-6 times the potency of tolbutamide
HORMONES					
Sex Hormones					
estrone USP, theelin	many products	1939	St. Louis U., Schering, Germany	Abbott, P-D	First crystalline estrogen
estrogenic substances, conjugated	Premarin, Amnestrogen, Conestron, Estrifol, Konogen	1943	Ayerst, Canada	Ayerst, U.S.A. (C)	Orally effective natural estrogens
methyltestosterone USP	Metandren, Neo-Hombreol M, Oreton M, Synandrotabs	1947	Ciba, Switzerland	Ciba, U.S.A. (C)	The orally effective form of testosterone
chlorotrianisene	Tace	1952	Merrell	Merrell	Synthetic estrogen, very effective orally, stored in body fat with slow release
hydroxyprogesterone caproate	Delalutin	1956	Schering, Germany	Squibb (C)	Long acting progesterone for treatment of corpus luteum insufficiency

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
		Sex Hormones (Contd)			
norethandrolone	Nilevar	1956	Searle	Searle	Synthetic anabolic androgen equal to testosterone in anabolic activity, but with only 1/16 the androgenic effect
norethynodrel	Enovid contains this plus another estrogen	1957	Searle	Searle	Enovid closely mimics the action of the corpus luteum hormone; orally effective progestogen; known to have contraceptive effects
norethindrone	Norlutin	1957	Syntex, Mexico	F-D	One of the most potent oral progestational compounds known; also inhibits ovulation
fluoxymesterone	Halotestin	1957	UpJohn	UpJohn	Produces all of the metabolic and clinical effects of methyl-testosterone and testosterone, but is more potent than either
		Corticosteroids			
prednisone USP	Meticorten, Deltra, Deltasone, Paracort	1955	Syntex, Mexico	Schering, U.S.A.	Corticosteroid several times as potent as cortisone
methylprednisolone	Medrol	1957	UpJohn	UpJohn	A new corticosteroid, effective in lower dosage than prednisolone and with fewer side effects
triamcinolone	Aristocort, Kenacort	1958	Lederle	Lederle, Squibb	Steroid with greater anti-inflammatory potency than prednisone and without sodium retaining and edema-producing effects of other glucocorticoids

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
Corticosteroids (Contd)					
dexamethasone	Decadron, Dexonil, Gammacorten	1958	MSD, Schering, U.S.A.	MSD, Schering, U.S.A.	Anti-inflammatory steroid with little salt retention; approximately 7 times as potent as prednisone
TRANQUILIZERS & CENTRAL NERVOUS SYSTEM DRUGS					
Tranquilizers					
chlorpromazine USP	Thorazine	1954	Rhône-Poulenc, France	SKF	First drug for specific treatment of mental disease to be introduced in the U.S.
meprobamate	Miltown, Equanil, Meprospan, Meprotabs	1955	Wallace	Wallace	Central interneuronal blocking agent with mild tranquilizing activity; muscle relaxant
promazine	Sparine	1955	Rhône-Poulenc, France	Wyeth	Tranquilizer for the treatment of acute neuropsychiatric agitation
hydroxyzine	Atarax, Vistaril	1956	Union Chimique, Belgium	Roerig	Tranquilizer with low incidence of toxicity
perphenazine	Trilafon	1957	Schering, U.S.A.	Schering, U.S.A.	For treatment of psychoneuroses characterized by anxiety, tension, and agitation; also an antiemetic. Useful in some cases resistant to treatment with other psychochemicals
phenaglycodol	Ultran	1957	Lilly	Lilly	Mild tranquilizer used to produce a calming effect in patients with emotional instability and anxiety-tension states
prochlorperazine	Compazine	1957	Rhône-Poulenc, France	SKF	Tranquilizer which produces no drowsiness or depression. Has pronounced antiemetic properties.

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Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
Tranquilizers (Contd)					
trifluoperazine	Stelazine	1958	SKF	SKF	Relieves anxiety and restores normal drive in patients who are apathetic, listless and emotionally fatigued
trimeprazine	Temaril	1958	Rhone-Poulenc, France	SKF	First specific for treatment of pruritus regardless of cause
Antidepressants					
phenelzine	Nardil	1959	W-C	W-C	Antidepressant effective in treating true depression without overstimulation
nialamide	Niamid	1959	Pfizer	Pfizer	Psychotherapeutic antidepressant effective in a wide range of depressions
imipramine	Tofranil	1959	Geigy, Switzerland	Geigy, U.S.A. (C)	Antidepressant effective in very severe depressions; frequently permits elimination of electroconvulsive therapy in psychopathologic states
Muscle Relaxants					
methocarbamol	Robaxin	1957	Robins	Robins	Long-acting skeletal muscle relaxant which selectively blocks multisynaptic reflexes in muscle spasm and pain with no known contraindications

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
Muscle Relaxants (Contd)					
chlorzoxazone	Paraflex	1958	McNeil	McNeil	Skeletal muscle relaxant for use in musculoskeletal disorders; has shown very low toxicity
Trancopal	chlormethazanone	1958	Winthrop	Winthrop	Muscle relaxant and tranquilizer for use in a variety of musculoskeletal and neurologic conditions as well as anxiety and tension states
Soma	carisoprodol	1959	Wallace	Wallace	Muscle relaxant with analgesic properties used to restore mobility in musculoskeletal disorders
Anorexigenics					
phenmetrazine	Preludin	1956	Geigy, Switzerland	Geigy, U.S.A. (C)	Anorexigenic agent with less stimulation than amphetamine
diethylpropion	Tenuate, Tepanil	1959	Tenaler, Germany	Merrell, National	Appetite-suppressant without any stimulant effects
Antinauseants					
dimenhydrinate USP	Dramamine	1949	Searle	Searle	Antinauseant for use in treatment of motion sickness, Ménière's syndrome, labyrinthine disorders and nausea produced by drugs and pregnancy
meclizine	Bonamine	1955	Union Chimique, Belgium	Pfizer (C)	Antinauseant for treatment or prevention of motion sickness and nausea and vomiting associated with vertigo, labyrinthitis, Ménière's syndrome and radiation sickness

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
Antiepileptics					
diphenylhydantoin USP	Dilantin	1938	Kiel U., Germany	P-D	First successful non-barbiturate antiepileptic agent; is not a sedative. Was the basis for studies on structure-activity relationships of compounds to the convulsive process.
primidone	Mysoline	1954	ICI, England	Ayerst (C)	Antiepileptic for use in control of grand mal and psychomotor seizures. No serious toxic reactions have been reported.
Sedatives					
pentobarbital USP	Nembutal	1930	Bayer, Germany	Abbott	Short-acting barbiturate particularly useful in preoperative sedation of children
mephobarbital	Mebaral	1935	I.G. Farben., Germany	Winthrop	Barbiturate sedative with anticonvulsant activity which makes it particularly useful as an antiepileptic with minimal hypnotic activity
butabarbital	Butisol	1937	Lilly	McNeil	Intermediate-acting barbiturate used as a sedative or hypnotic; nontoxic to the liver
glutethimide	Doriden	1954	Ciba, Switzerland	Ciba, U.S.A. (C)	Nonbarbiturate hypnotic and sedative; short-acting
Analgesics					
meperidine USP	Demerol	1944	I.G. Farben., Germany	Winthrop	Narcotic analgesic having spasmolytic activity without the hypnotic side effects of morphine

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
			Analgesics (Contd)		
phenylbutazone	Butazolidin	1952	Geigy, Switzerland	Geigy, U.S.A. (C)	Nonopiate, nonaddicting analgesic with anti-inflammatory activity, particularly useful in management of musculoskeletal disorders including gout, arthritis, bursitis, etc.
dextro propoxyphene	Darvon	1957	Lilly	Lilly	Analgesic, comparable in potency to codeine, with little or no side effects or addiction liability
			Local Anesthetic		
Lidocaine	Xylocaine	1949	Astra, Sweden	Astra, U.S.A. (C)	Potent local anesthetic, about twice as potent as procaine; used for infiltration and block anesthesia as well as topically on mucous membranes
			Sympathomimetics		
phenylephrine USP	Neo-Synephrine	1934	Boehringer, Germany	Stearns	One of the most widely used topical nasal decongestants
dextro amphetamine USP	Dexedrine	1944	SKF with private inventor as consultant	SKF	Sympathomimetic agent as CNS stimulant in mental depression, fatigue, narcolepsy and parkinsonism. Also employed for anorexigenic effect in obesity.

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
Sympathomimetics (Contd)					
methylphenidate	Ritalin	1956	Ciba, Switzerland	Ciba, U.S.A. (C)	Mild cortical stimulant for treatment of various types of depression, either psychological or drug-induced. Particularly suited for use in hypertensive patients since oral use does not affect blood pressure.
CARDIOVASCULAR-RENAL DRUGS					
Diuretics					
acetazolamide	Diamox	1953	Lederle	Lederle	The first orally effective, nonmercurial diuretic, a carbonic anhydrase inhibitor.
chlorothiazide	Diuril	1958	MSD	MSD	Effective oral diuretic; hypotensive
hydrochlorothiazide	Hydrodiuril, Esidrix	1959	MSD, Ciba, U.S.A.	MSD, Ciba, U.S.A.	More potent oral diuretic; hypotensive
Hypotensives					
hydralazine	Apresoline	1952	Ciba, Switzerland	Ciba, U.S.A. (C)	One of the first compounds to provide significant lessening of systolic and diastolic pressure
Rauwolfia serpentina, whole root	Raudixin	1953	Sen, C., India	Squibb	Presumably through its action on the central nervous system, it lowers blood pressure and slows the pulse rate.
reserpine USP	Serpasil	1953	Ciba, Switzerland	Ciba, U.S.A. (C)	Potent antihypertensive; crystalline alkaloid of Rauwolfia root.

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
			Hypotensives (Contd)		
pentolinium	Ansolysen	1954	May & Baker, England	Wyeth (C)	Ganglion blocker; reduces malignant, severe and moderately severe hypertension
			Others		
tolazoline USP	Priscoline	1948	Ciba, Switzerland	Ciba, U.S.A. (C)	Peripheral vasodilator; previously there had been no effective treatment for peripheral vascular disease but surgery.
pentaerythritol tetranitrate	Peritrate tetranitrate, Pentafin, Quintrate	1950	Bjerlov, H., Sweden	W-C	A vasodilator with prolonged action
nylidrin	Arlidin	1954	Troponwerke Dinklage, Germany	Arlington	Peripheral vasodilator with site of action of other sympathomimetic drugs, but only a vasodilating effect.
			ANTIHISTAMINICS		
diphenhydramine USP	Benadryl	1946	P-D	P-D	Antihistamine with antispasmodic activity; first successful synthetic antihistamine
chlorpheniramine USP	Chlor-Trimeton	1949	Schering, U.S.A.	Schering, U.S.A.	Antihistamine with low incidence of side effects; presently used in hundreds of products.
tripelennamine USP	Pyribenzamine	1949	Ciba, U.S.A.	Ciba, U.S.A.	Antihistamine with low incidence of side effects

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ANTIHISTAMINICS (Contd)					
promethazine	Phenergan	1951	Rhône-Poulenc, France	Wyeth (C)	Antihistamine useful for surgical and obstetric sedation and to control nausea and vomiting, particularly when associated with operative surgical procedures, pregnancy or vomiting of reflex origin.
ANTICHOLINERGICS					
dicyclomine	Bentyl	1950	Merrell	Merrell	Anticholinergic with effect on both upper and lower intestinal tract; also useful in treatment of functional intestinal distress. Virtually free of atropine-like side effects.
propantheline	Pro-Banthine	1953	Searle	Searle	Has side effects less severe than its predecessor, methantheline.
ENZYMES					
hyaluronidase USP	Wydase, Alidase, Hyazyme	1949	Rockefeller Inst.	Wyeth	First lyophilized hyaluronidase, purified, standardized and stabilized for predictable results. Facilitates spread and absorption of injected solutions.

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ENZYMES (Contd)					
streptokinase-streptodornase	Varidase	1949	Lederle Labs.	Lederle (C)	Enzyme combination which liquefies clotted blood, pus and other debris.
HEMOSTATICS					
aminocaproic acid	Amicar	1957	Wyeth	Wyeth	Hemostatic which inhibits fibrinolysis.
HORMONES					
chorionic gonadotropin	Follutein	1931	Zondek & Aschheim	Ayerst (C)	Hormone which stimulates ovulation and corpus luteum formation.
corticotropin	ACTH	1933	Collip	Armour (C)	Hormone which stimulates adrenal cortex.
cosyntropin	Cortrosyn	1963	Organon, Holland	Organon	Synthetic hormone which stimulates adrenal cortex.
desoxycorticosterone acetate	Doca	1939	Ciba, Switzerland	Ciba	Hormone which regulates electrolyte balance.
estradiol	Estrace	1933	Doisy	Mead Johnson (C)	Estrogen.
estrogens, conjugated	Premarin	1942	Ayerst	Ayerst	Estrogen.
estrone	Theelin	1929	Doisy	Parke-Davis (C)	Estrogen.
ethinyl estradiol	Estinyl	1938	Inhoffen, Germany	Schering	Estrogen.
fluoxymesterone	Halotestin	1956	Upjohn	Upjohn	Androgen.
methyltestosterone	Testred	1939	Ruzicka, Switzerland	Schering	Androgen.
progesterone	Progesterone	1934	Allen & Wintersteiner	Upjohn (C)	Hormone which prepares uterus for implantation of fertilized ovum.
testosterone	Testosterone	1935	Ruzicka, Switzerland	Ciba (C)	Androgen.

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ENZYMES (Contd)					
trypsin	Parenzyme, Tryptar	1951	Rockefeller Inst.	National	For rapid reduction of acute local inflammation in phlebitis, etc.
streptokinase-streptodornase	Varidase	1951	N.Y. U.	Lederle	For nonsurgical debridement
chymotrypsin	Chymar, Enzeon	1955	Rockefeller Inst.	Armour	Relieves inflammation and promotes healing through systemic action.
penicillinase	Neutrapen	1958	SchenLabs	SchenLabs	First penicillinase suitable for human use, for prophylaxis and treatment of penicillin allergy.
ANTINEOPLASTIC AGENTS					
mechlorethamine	Mustargen	1949	Leeds U., England	MSD	The discovery that nitrogen mustard is a palliative in certain forms of neoplastic disease opened a new avenue of therapy.
6-mercaptopurine	Purinethol	1953	B-W, U.S.A.	B-W, U.S.A.	Metabolic antagonist of hypoxanthine and adenine which will provide temporary remission in acute leukemia and chronic myelogenous leukemia.
cyclophosphamide	Cytoxan	1959	Asta, Germany	Mead Johnson (c)	More effective against some forms of cancer with fewer side effects than older drugs
chlorambucil	Leukeran	1957	Chester Beatty Res. Inst., England	B-W, U.S.A. (c)	Treatment of leukemia, malignant lymphomas and Hodgkin's disease; produces fewer side effects than nitrogen mustard.

Generic Name	Trade Name(s)	Year	Discoverer	Developer	Significance
ANTINEOPLASTIC AGENTS (Contd)					
triethylenethiophosphoramide	thio-tepa	1959	Lederle	Lederle	Has yielded consistent palliative results in several neoplastic diseases

ABBREVIATIONS

(C) - Clinical development
B-W - Burroughs-Wellcome
ICI - Imperial Chemical Industries
MSD - Merck Sharpe & Dohme
P-D - Parke, Davis
SKF - Smith, Kline & French
W-C - Warner-Chilcott

Trade-marks are capitalized; generic names are not.

Prepared by:

Eleanor Buckley, Wyeth
Herb Engelbert, Smith, Kline & French
Winifred Sewell, Chairman, Squibb

March 17, 1960

It is the responsibility of our industry to take advantage of drug progress, wherever it is made. Those who disparage the industry for doing so fail to recognize that the greatest tragedy in medicine is for a discovery to lie idle in a laboratory. The real boon to the world is getting a discovery developed, tested, and into the corner drugstore where it is available to save lives. This is a vital service to the American people. It reflects favorably upon the U.S. pharmaceutical industry.

Too often there has been unnecessary quibbling over discovery. The pharmaceutical industry has made, is making, and will make more than its share of discoveries. But even more important is the fact that the industry will expand its research to determine how to use, then make for use, these discoveries, and in addition, the discoveries of others. Without this research, which includes the research of development, most discoveries would remain at best scientific curiosities.

Senator KEFAUVER. All right, sir. Is there anything else?

Dr. SMITH. Yes. During the past 2 or 3 weeks, and during the February session, in which I took part, there were statements to the effect that medicine and the pharmaceutical industry had differences of opinion, which is inevitable in the American way of life, but there were other charges made, to which there should be a reply. I would like to assure you at this time that there will be no comment on individual statements or on individuals. But I would like to reply to some general charges that have been made by a number of individuals because I feel without making use of this opportunity to supplement our original statement, there would be no chance for the medical profession, at this time at least, to indicate its attitudes.

One statement has been made that editorial space in medical journals is available in return for dollars paid to the advertising department.

Senator DIRKSEN. What page are you on, Doctor?

Dr. SMITH. This is not in the manuscript, Senator Dirksen. I have several things to which I wish to address myself, because of the serious accusations that have been made during the past 2 or 3 weeks.

The charge or the implied charge or accusation, that editorial space can be bought is a most damaging one for medicine and for medical associations, and for pharmacy and pharmaceutical associations. Without going into details, insofar as other associations are concerned, I can say that the American Medical Association, from my past experience, clearly separates its editorial and business departments. Certainly in the almost 20 years that I spent with the American Medical Association, there was no indication at any time that an advertisement in any way influenced an editorial article, or that an editorial article, in turn, influenced an advertisement or the solicitation of advertising. These were independent departments.

This is true also for many of the State medical journals, and I would refer you to the State journal advertising bureau, which is responsible for more than 30 State medical journals. This has similar policies, to the best of my knowledge, and both of these bodies, the AMA and the State journal advertising bureau, in addition screen ads very carefully. There has been some criticism about the adver-

tisements appearing in medical journals, and this too I believe is an unfortunate and unjust criticism. Again to speak specifically about just two of these organizations, since I know them well: The American Medical Association for many years has had an advertising committee, which is dependent on its council on drugs, the old council pharmacy, and chemistry and many other consultants who are experts in the fields of drugs to advise it in the acceptance of advertisements and the claims made in these advertisements, and to the best of my knowledge, this policy still holds true. The State journal advertising bureau follows similar objectives for many States medical journals. In addition, there are other journals—I will name only one—that have their own advertising boards or screening committees. One well known one is the California State Medical Association Journal, which certainly has a group of able clinicians advising on the acceptance of advertising. So I think the record should show two things. First in my conviction, editorial space cannot be bought by advertisements. And frankly, I would have no part of medicine or industry if it could be; second, advertisements are screened in medical journals, and those with which I would have any association have been so screened.

Senator KEFAUVER. Dr. Smith, these were statements by reputable physicians, several whom have been medical directors of leading pharmaceutical houses and who have had practical experience with the development and advertising of drugs. These are not statements by the subcommittee, these are statements by a number of physicians who have testified before the subcommittee.

Dr. SMITH. But these were statements made by individuals who are not now associated with the drug industry. And I believe that perhaps it would be helpful to the subcommittee if individuals from the industry were called to reveal what the practices are in the industry.

Senator KEFAUVER. As you very well know, we have had before us, Schering, Upjohn, Merck, Smith Kline & French, Carter, and American Home, among others. And we have asked them about some of these matters from time to time. But you may proceed, sir.

Dr. SMITH. Thank you, sir.

A statement has been made also that industry does not put money behind research to the extent that it should, and one particularly damaging statement was that there was no industry money behind the development of penicillin. Rather than take your time, sir, and the time of the subcommittee in detail, let me simply say that this is not true, that there were many millions of industry dollars put behind the development of penicillin, and I will file for the committee a statement supporting my reply to this charge.

Senator KEFAUVER. Let that be filed as exhibit 268.

(Exhibit No. 268 may be found on p. 10963.)

Dr. SMITH. Another statement has been made, and this one repeatedly, that physicians do not read mail which is sent to them. There are several excellent examples to disprove this.

Senator KEFAUVER. I don't remember anybody who said that. I heard the statement made that——

Senator DIRKSEN. I did, Mr. Chairman. It was said in your absence by one of the witnesses.

Senator KEFAUVER. In any event the witnesses I have heard said that some did and some did not.

Senator DIRKSEN. Well, what the witness said on that occasion was that they didn't read it, it went into the wastebasket. And I think, Dr. Smith, you certainly are entitled to make a statement on that.

Dr. SMITH. Thank you, sir. My only reason for raising the issues is so that the record be clear, because I am not here just to talk about the drug industry, Mr. Chairman; I am here to talk about a way of life, an American way of life. And so I think the record should be clear. Concerning this statement, I would just draw to your attention two things, and then comment on two additional things.

First, there was a survey, conducted by the American Medical Association, with the concurrence of the American Pharmaceutical Manufacturers Association and the American Drug Manufacturers Association——

Senator KEFAUVER. Dr. Smith, you referred to that survey earlier.

Dr. SMITH. You do not wish me to——

Senator KEFAUVER. I don't mind your referring to it.

Dr. SMITH. Thank you. Under the circumstances, I would remind the subcommittee that it is available. I would also remind the subcommittee that there has been a study made under the sponsorship of the Fisher-Stevens agency, which clearly reveals, as did the AMA report, the attitude of the medical profession toward direct mail and toward detail men. And in addition, as a specific example, I would refer to one firm which sent out a mailing on January 28, 1960, to 155,000 physicians, saying that if the physician wished to reply by forwarding or returning a card, the physician could obtain certain additional information. This first mailing returned 49,600 requests—a 32-percent return. The second mailing went to these physicians in February, 1 month later, and this brought 49,000 returns. It brought a total net response of two mailings of 77,000. And a third resulted in a total response of 106,000 from the medical profession.

Now, one final thing in connection with mail. A statement was made a few days ago that the drug industry undertook tremendous expenditures in the promotion of its products. I would like to draw your attention to just three or four statements made to prove that there is good reason for my suggestion that you get facts on this from others.

There was a statement made, for example, in the table filed with the witness' statement with the subcommittee, that Wallace Laboratories spent a little more than a million and a half dollars in advertising, direct mail, and samples in December 1959. I have made inquiry, which seemed to me the logical thing to do from the firm, and asked for information and facts. And I find that that accusation is not so. Actually, the firm that month in that year, spent just a little less than $420,000. This involved nine products, which meant there was about an expenditure of roughly $46,000 per product, for 100,000 doctors,

not 150,000 doctors, as was stated in this witness' presentation. And that works out to about 46 cents per doctor for the month.

Another firm was accused of spending $3,600,000—$3,600,000 in a direct mailing in October 1957 to 150,000 physicians; on inquiry, it turns out that this direct mail went only to 6,000 newly practicing physicians—the men who turned from their internships and residencies into practice. This mailing was intended to acquaint these new physicians with the products available from this firm and it involved an expenditure of $108,000, not more than $3 million.

Another firm was said to have spent almost $300,000 on circulars and samples sent to 150,000 physicians in December 1959, and this firm on inquiry revealed that it spent a little more than $132,000, and the number of physicians addressed on a given piece ranged from 1,700 to 141,000.

Another firm was accused of spending $296,000. It spent $65,000.

Now, I think, Mr. Chairman, that men from industry, if given an opportunity to explain their expenditures, would be able to reveal for the subcommittee the true situation, and you would not have to depend on estimates or at best poor "guesstimates."

Senator KEFAUVER. Well, sir, we have the figures supplied to us by the companies as to what their selling and other costs are. Of the sales dollar in 1958, 24 cents included the selling cost. That is according to company figures.

Senator HRUSKA. If the chairman would yield, it seems to me the testimony of the witness last week was directed to particular months, to particular companies, and the witness has just addressed his reply to particular months to particular companies, and the exhibit to which the chairman has just referred has no relevance to those points at all.

Senator KEFAUVER. This is relevant in that it refers to the large companies from which information was sought.

Senator HRUSKA. But the witness to whom reply is being now made by Dr. Smith didn't touch on these companies. He didn't touch on overall sales, development, and promotional expense. He was only generalizing and speculating as to specific companies for specific months on some mailings which he received. So if the chairman would now seek to generalize from that generality and speculation to another speculation, we are going to have quite a strange record, it seems to me.

Senator KEFAUVER. If the Senator desires, we can put in the figures by each of the companies. We have that information for the last year it was available.

All right, you may proceed.

Senator DIRKSEN. Well, let's get this point cleared up.

Mr. Chairman, that is the sales dollar allocated to selling—there is something in selling besides advertising.

Dr. SMITH. Mr. Senator, and Senator Dirksen, I of course have information from representative firms in that respect, and at a later time if you wish to discuss it, I could do so. I didn't wish to bring it up at this time for the simple reason I was trying to conserve your time and address myself to some of the misleading statements that have been presented before this subcommittee during the past weeks and months.

Senator KEFAUVER. Very well. We will put this information into the record as reported by these 20 companies, with the breakdown of the 24-cent selling cost.

(The document referred to, Exhibit No. 160, may be found in part 16, p. 9176.)

Dr. SMITH. That is your statement, sir. I assume that also in the record would go my reply to some of the comments here.

Senator KEFAUVER. These are the company figures. If you have anything else you want to put in the record——

Dr. SMITH. The information I just read to you I would be pleased to put in the record, and I presume it is going in the transcript, too.

Senator KEFAUVER. Very well. It will be exhibit 269.

(Exhibit No. 269 may be found on p. 10963.)

Dr. SMITH. Now, another thing that has been said repeatedly is that doctors are swamped with mail. You know that I am a physician. I am licensed in Canada. I am on the mailing list for mailing houses. I collected samples for 19 days. And an associate of mine will show you what can be dumped out of a box in 19 days, and this box is about half the size of what was in a box that we saw before. This is all there is that was collected in 19 days.

Senator KEFAUVER. Let's get this straight. Does this refer to mail addressed to you in Canada?

Dr. SMITH. This is addressed to me at my present office address.

Senator KEFAUVER. But you are not licensed to practice in the United States.

Dr. SMITH. I am licensed in Canada. I am carried as a licensed physician, and I am on the mailing list of all physicians, as far as I know, except for specialties. Now one thing that is overlooked——

Senator KEFAUVER. I assume that on the lists are all the practicing physicians in the United States. But you are not licensed to practice in the United States.

Senator DIRKSEN. That is not a fair assumption.

Dr. SMITH. No; that is quite true, Senator. There is no need for me taking a license in the District of Columbia, for example. I don't see patients. Nor was there any need for me to do so in Illinois, when I was with the American Medical Association. I am not talking about licensing, Mr. Chairman. I am talking about physicians who are qualified to receive mail, being on a mailing list.

Now, one thing that has been overlooked very frequently, and in the discussions presented to this subcommittee, is that mailings are selective, and they may go to general practitioners or to specialists. They don't necessarily go to 150,000-odd practicing physicians, each time a mailing is put out.

Senator KEFAUVER. A Minnesota doctor sent us a boxful of mail, and we received several boxes full from other doctors. But I would think that there would be a difference between a practicing physician in the United States and one who is not licensed to practice in the United States, as to the amount of promotional material he would get.

Dr. SMITH. My feeling is if you were to ask mailing houses and firms about this, that the answer would be available.

Senator KEFAUVER. I think the information would be more accurate coming from a practicing physician in this country, Dr. Smith.

Dr. SMITH. Well, I think that too reflects a matter of personal experience.

Senator KEFAUVER. Very well. You are not implying that the Minnesota doctor who sent us this boxful which he collected in a month did not actually receive all of it?

Dr. SMITH. I am not implying anything about any of the preceding witnesses. I am merely saying that I think that the record has been so confused in some places, that this subcommittee could be helped considerably if it would obtain information from other sources.

Senator KEFAUVER. We are doing the best we can, sir. You proceed, sir.

Senator DIRKSEN. Well, Doctor, I just want to observe that certainly a country doctor would welcome any information that comes along. You can call it what you like. I don't think this question of how much mail a doctor receives is world-shaking in its importance. And I have an idea that if he has time between patients, he likes to take a look at some of these circulars, advertisements; it keeps him abreast of the times. What is wrong with that, I would like to know?

Senator KEFAUVER. The only question concerns advertising, selling and——

Senator DIRKSEN. Now, that chart says selling, not advertising.

Senator KEFAUVER. I am referring to advertising and selling. It is costing the manufacturer 24 cents out of the sales dollar. If that could be reduced, of course, the price of medicine could be reduced to the patient.

Senator DIRKSEN. Dr. Smith, I thought you were talking about direct mail.

Dr. SMITH. I am—direct mail and samples.

Senator DIRKSEN. Which is a mighty different thing from what this chart shows. That shows selling. And selling means everything—the men on the road, advertising, every other element of cost that goes into it, and anybody who has been in business knows better than to just take advertising and set it apart and say "Well, there is the selling cost." It is not anything of the kind.

Senator KEFAUVER. Selling includes advertising, direct mail, and detail men—and it takes 24 cents of every dollar spent for medicine.

Dr. SMITH. Well, Mr. Chairman, to conserve your time, there are just two or three other points to which I would like to address myself in the presentation of this material.

Another statement that has repeatedly appeared in various places, and, I am afraid, by inference in some of the statements during the past few months made to the subcommittee, is the lack of conscience on the part of the pharmaceutical industry in providing public services. I have attempted to compile for the first time a story of the public service of American drug manufacturers, and I would not take your time now to introduce this into the record. Furthermore, it is not yet completed. However, in chart 15 there is an example——

Senator KEFAUVER. We will make that exhibit 270, sir.

(Exhibit No. 270 follows:)

Exhibit 270

Many Items Are Made For Rare Diseases, Without Hope Of Financial Return

Products	Indications	Known Cases (In 1959)	Manufacturers
Acetyl Strophanthidin Ampules	Only for critical cases of congestive heart failure	150	Eli Lilly
Antipertussis Serum	For passive immunization or early treatment of whooping cough	Less than 4,000	Wyeth
Antivenin	To neutralize snake venom	Less than 5,000	Wyeth
Arbesol	To minimize blood loss in brain surgery	8,000	Roche
BAL in Oil Ampules	For heavy metal poisoning	A few thousand	NWD
Bone Wax	For patching skull in selected cases of brain surgery	Less than 1,000	HWD
Calcium Disod. Versenate	To treat lead poisoning	9,000	Riker
Colchicine Ampules	For acute cases of gout	75	Eli Lilly
Cortate	To treat Addison's disease	12,000	Schering
Dandy's Solution	To visualize sinuses for possible pathology as diagnostic agent prior to brain surgery	Less than 2,000	HWD
Direct Sky Blue	For detection of cancerous tissue in surgery	Less than 1,000	Wyeth
Ecelid	For exceptionally severe, malignant hypertension	10,000	Ciba
Sodrate Disodium Solution	For treatment of scleroderma or certain pathologic calcification	10,000 to 15,000	Abbott
Fluorinef Tablets	To treat Addison's disease	10,000	Squibb
Fungizone Infusion	For deep-seated mycotic infections, particularly histoplasmosis	Less than 5,000	Squibb
Glutavene	For emergency treatment of coma associated with certain liver ailments.	8,000 to 10,000	Cyanamid-Barnes
Ketonil	To prevent mental deterioration of infants and children with phenylketonuria	Less than 1,000	Merck
Lofenalac	To prevent mental deterioration of infants and children with phenylketonuria	Less than 1,000	Mead Johnson
Lygranox C. F.	For lymphogranuloma venereum	Less than 2,500	Squibb
Lyovac Antivenin	To counteract potentially fatal bite of the black widow spider	1,700	Merck
Lyovac Tetanus Antitoxin (Equine)	To treat tetanus in patients sensitive to antitoxin made from horses	18,200	Merck
Megimide	To counteract coma due to overdosage of barbiturates	12,000	Abbott
Mestinon	In symptomatic treatment of myasthenia gravis	8,500 to 15,000	Roche
Modenalin	To treat ammonia intoxication due to hepatic failure	10,000	Abbott
Pavadrine Hbr Tablets	In treatment of heart block	Less than 1,000	SKF
Quinidine (IC) Injectable	For emergency injection to treat ventricular tachycardia and auricular fibrillation	Less than 10,000	Brewer
Rare Human Blood Fraction	For maintenance of patients with hemophilia B	5 people or less	Cutter
Rolanon	For treatment of scleroderma	15,000	Warner-Chilcott
Sosie (D40)	To reduce dangerously high concentration of potassium in renal failure	300	SKF
Sodium Thiocyanate Amps	For very critical, almost terminal hypertension	15	Eli Lilly
Sodium Versenate	To treat digitalis intoxication	1,250	Riker
Spirodon	For rare form of epilepsy	30	Cutter
Tensilon	As a curare antagonist; and for hard-to-diagnose cases of myasthenia gravis	6,500 to 15,000	Roche
Unitensen Aqueous	To relieve acute vasospasm in convulsive toxemia	10,000	Irwin, Neisler
Vivdril	For anesthesia in head, neck, and chest surgery for poor-risk patients; and in bronchoscopy	750	Pfizer

35621 O—60—pt. 19——17

Dr. SMITH. Thank you, sir. In chart 15 there is an example of the many items that are made by pharmaceutical houses for rare diseases without any hope of financial return.

And I think you will find many diseases and many firms listed there.

Now, in addition there is another way in which the pharmaceutical industry attempts to meet its obligations as a public servant, and that is in the supplying of material to those who have need for it—the poor and those who are in other parts of the world—which helps bring a better appreciation of Americanism. Could I have your permission to have a witness who is with me speak to that for 2 or 3 minutes—Dr. Walsh of Project Hope?

Senator KEFAUVER. Dr. Smith, we would rather get on with your examination, and let anybody else come later, if we can.

Dr. SMITH. Yes, sir.

Senator DIRKSEN. Well, this would be the appropriate time, Mr. Chairman. He says he will take only a few minutes. After all, what is time to this subcommittee? We have been here so long.

Senator KEFAUVER. I don't know whether the Senator is going to object at 12 o'clock.

Senator DIRKSEN. I actually got you permission to sit the other day, Mr. Chairman.

Senator KEFAUVER. Will you do the same today?

Senator DIRKSEN. I shall do the same today, even though we have a controversial nomination on the floor—if you will give me a vote for the nominee. But if it is only going to take a few minutes, this is the appropriate time to hear from Dr. Walsh.

Senator KEFAUVER. Where is Dr. Walsh?

Dr. SMITH. Right here.

Senator KEFAUVER. If you will speak briefly, please. We want to get on with Dr. Smith, if we can.

Dr. WALSH. Yes, sir.

STATEMENT OF DR. WILLIAM B. WALSH, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, D.C.

Dr. WALSH. Senator, members, I am Dr. William B. Walsh, a practicing physician, Washington, D.C., assistant clinical professor of internal medicine of Georgetown University School of Medicine, and president of the People to People Health Foundation, the sponsoring organization of Project Hope.

When Dr. Austin Smith asked me to appear with him before this committee, I considered it a privilege and an honor. There are hundreds of organizations in the United States similar to our foundation which devote their time and effort to improving the health opportunities for less fortunate persons both at home and abroad.

These number among their members the missionaries of every faith and an increasing number of voluntary groups from the health professions.

Their purpose is not only to heal the sick, but also to improve, by means of teaching and training, the abilities of the people of newly independent nations to help themselves.

These efforts are sponsored by the American people through public subscription and, in even greater measure, by the support of industry and labor. The result is of benefit to the recipient and in addition does much to improve the posture of the United States throughout the world. The voluntary support of this type of effort on a nongovernmental level is peculiar only to the people of the United States.

I make this preface to my brief remarks, too, so that you will understand my reasons for feeling the privilege of which I spoke.

I believe that were each of these groups provided an opportunity, you would be told of the unselfish attitude and unstinting support given to each of us by the great pharmaceutical industry. In my own experience, I have never asked for an iota of support in funds or drugs, on the basis of potential profit or future market.

My only plea to the numerous executives with whom I have spoken has been based upon the appeal of help to the needy and the obligatnion of good citizens to improve the understanding of the people of the United States by others throughout the world. I have never been refused.

The initial funds required for Project Hope, for example, were supplied by the pharmaceutical industry, and the drugs necessary were assured a year ago. I am not aware of any just request by any comparable organization ever having been refused by the industry.

In truth, without the knowledge beforehand that drugs would be provided, there is hardly a nongovernment medical mission that could succeed or even exist without this beneficence on the part of the pharmaceutical industry.

It should be recognized for what it is—compassion for the needy and a deep sense of the duties of American citizenship.

I am well aware that every one of you know the value of waging the peace during these critical times. There is no better way than to take advantage of the universal language of medicine.

There are no barriers of race, creed, or political belief when a man is in pain or debilitated by poor health. This industry has been making possible the improvement of the lot of mankind from its very inception without thought of personal gain or benefit.

I could go on at considerable length, but I know the press of time. I felt a deep sense of obligation on my part to bring before this committee the feelings of not only a few but rather a multitude of people who wished for you to have this knowledge added to your accumulated records and testimony.

As a physician, a teacher, and a foundation executive, I wish to register my feeling that the people of America owe much to this industry—more than ever will be realized by them.

There is not a needy patient in my practice who has had to purchase drugs; there is hardly a medical school that has not benefited from industry-supported research, and there is not a medical foundation that could exist for long without the continuing help of the pharmaceutical companies of this country.

Thank you very much for allowing me the time to make this brief statement.

Senator KEFAUVER. Thank you, Dr. Walsh. I think it is very fine of the pharmaceutical industry, and other industries, to support projects abroad. But it is understood, of course, that this is part of their operating expense that is charged off on their income tax.

Dr. WALSH. Well, I don't think, Senator, that that is the motivation with which it is provided. I would hate to think that this would be the picture provided to the people of the world, that our beneficence in America is traced only to our income tax.

Senator KEFAUVER. No; I don't mean that, but I mean this is an expense that they have a right to charge off, and of course they do.

Dr. WALSH. But no obligation, Senator; it is a privilege.

Senator KEFAUVER. All right, thank you.

All right, Dr. Smith.

STATEMENT OF DR. AUSTIN SMITH—Resumed

Dr. SMITH. Thank you, Mr. Chairman.

There has been considerable discussion of trade names versus generic names, and it seems to me that a threat has been woven through many of the hearings which demands a followup on the part of the PMA.

There are several pieces of information to which I would like to direct your attention. Comments will be brief. And I will summarize equally briefly these presentations after I have shown them to you.

Chart No. 7, which will be presented to you, indicates the various kinds of ointment bases that are used in an ointment that is applied to the skin. The only purpose in showing this to you is to demonstrate two things: First, that even a seemingly simple thing like an ointment involves many factors; and, second, this is a classification of ointment bases proposed and adopted by the AMA's Council on Pharmacy and Chemistry. And, incidentally, this appears in Sollman's "Textbook on Pharmacology."

Senator KEFAUVER. That will be exhibit No. 271.

(Exhibit 271 follows:)

Classification of Ointment Bases

The following has been adopted in New and Nonofficial Remedies:

I. Oleaginous Ointment Base (Bases consisting of hydrophobic hydrocarbon or nonhydrocarbon oils and greases.)

1. Anhydrous
2. Will not take up water
3. Insoluble in water
4. Not washable

Examples: lard
petrolatum
vegetable

II. Absorbent Ointment Base (Bases consisting of oleaginous materials mixed with emulsifying agents but no water.)

1. Anhydrous
2. Will take up water
3. Insoluble in water
4. Usually are not washable

Examples: anhydrous lanolin
hydrophilic petrolatum-U.S.P.

III. Emulsion Ointment Base

A. Emulsion Ointment Base W/O (Emulsions of water in oils.)

1. Hydrous
2. Will take up water
3. Insoluble in water
4. Not washable
5. Water-in-oil emulsions

Examples: cold cream
hydrous lanolin

B. Emulsion Ointment Base O/W (Emulsions of oils in water.)

1. Hydrous
2. Will take up water
3. Insoluble in water
4. Washable
5. Oil-in-water emulsions

Examples: hydrophilic ointment-U.S.P.
"vanishing creams"

IV. Water-Soluble Ointment Base

1. Anhydrous
2. Will take up water
3. Soluble in water
4. Washable
5. Greaseless

Example: polyethylene glycols

Dr. SMITH. Chart No. 8 shows the new admissions to the United States Pharmacopoeia.

Senator KEFAUVER. Make this exhibit 272.

(Exhibit 272 follows:)

☆ 225 DRUGS NEWLY ADMITTED TO U.S.P. XVI—WITH MONOGRAPHS

• Acetazolamide
Acetazolamide Tablets
Acetazolamide Sodium
Albumin, Radio-iodinated Serum
Aluminum Hydroxide Gel, Dried, Tabs
Aluminum Monostearate
Ammonium Chloride Tablets
Amodiaquine Hydrochloride
Amodiaquine Hydrochloride Tablets
Amphetamine Sulfate Injection
Anthralin
Anthralin Ointment
Atropine Sulfate Injection
Azurosin

• Barium Hydroxide Lime
Benoxinate Hydrochloride
Benoxinate HCl Ophthalmic Solution
Betazole Hydrochloride
Betazole Hydrochloride Injection
Bismuth Sodium Triglycollamate
Bismuth Sodium Triglycollamate Tabs
Blood Cells, Human
Blood-group Specific Substances A and B
Busulfan
Busulfan Tablets

• Calciferol Capsules
Calciferol Solution
Calcium Chloride Injection
Calcium Cyclamate
Calcium Cyclamate Solution, Compound
Calcium Cyclamate Tablets, Compound
Calcium Leucovorin
Calcium Leucovorin Injection
Calcium Pantothenate Tablets
Cetylpyridinium Chloride
Cetylpyridinium Chloride Solution
Chloral Hydrate Capsules
Chloramphenicol for Ophth. Solution
Chloramphenicol for Suspension, Sterile
Chloramphenicol Palmitate
Chloramphenicol Palmitate Oral Suspension
Chlorinated Oil
Chlorothiazide
Chlorothiazide Tablets
Chlorpheniramine Maleate Injection
Chlorpheniramine Maleate Syrup
Chlorpromazine HCl Injection
Chlorpromazine Hydrochloride Syrup
Codeine Phosphate Injection
Corticotropin Zinc Hydroxide Suspension, Sterile
Crotaline Antivenin, Polyvalent
Cyclizine Hydrochloride
Cyclizine Hydrochloride Tablets
Cyclopentolate Hydrochloride
Cyclopentolate HCl Ophth. Solution

• Desoxycorticosterone Acetate Tabs
Desoxycorticosterone Trimethylacetate
Desoxycorticosterone Trimethylacetate Suspension, Sterile
Dibucaine
Dibucaine Ophthalmic Ointment
Diethylcarbamazine Citrate Syrup
Diethyltoluamide
Dihydrotachysterol
Dimenhydrinate Syrup
Diphenhydramine HCl Injection
Diphenylhydantoin
Diphenylhydantoin Oral Suspension

• Edrophonium Chloride
Edrophonium Chloride Injection
Erythromycin for Injection
Erythromycin Oral Suspension
Erythromycin Ethylcarbonate
Erythromycin Glucoheptonate
Erythromycin Lactobionate
Erythromycin Stearate
Ethinyl Estradiol Tablets

• Fibrinogen

• Glycobiarsol
Glycobiarsol Tablets

• Hydrocortisone Sodium Succinate
Hydroxychloroquine Sulfate
Hydroxychloroquine Sulfate Tablets
Hydroxystilbamidine Isethionate

• Influenza Virus Vaccine
Insulin Zinc Suspension
Iodochlorhydroxyquin Ointment
Iodochlorhydroxyquin Tablets
Iophenoxic Acid
Iophenoxic Acid Tablets
Isoflurophate Ophthalmic Ointment

• Levallorphan Tartrate
Levallorphan Tartrate Injection
Lidocaine
Lidocaine Hydrochloride Injection

• Mecamylamine Hydrochloride
Mecamylamine Hydrochloride Tablets
Mechlorethamine Hydrochloride
Mechlorethamine HCl for Injection
Meclizine Hydrochloride
Meclizine Hydrochloride Tablets
Menadiol Sodium Diphosphate Inject
Menadiol Sodium Diphosphate Tablets
Mephobarbital
Mephobarbital Tablets
Meprobamate
Meprobamate Tablets
Mercaptopurine
Mercaptopurine Tablets
Methotrexate
Methylbenzethonium Chloride
Methylene Blue
Methylene Blue Injection
Methylglucamine Diatrizoate Injection
Methylglucamine Iodipamide Injection

• Nicotinamide Tablets
Nitrofurantoin
Nitrofurantoin Oral Suspension
Nitrofurantoin Tablets
Novobiocin Calcium
Novobiocin Calcium Oral Suspension
Novobiocin Sodium
Novobiocin Sodium Capsules
Nystatin
Nystatin Ointment
Nystatin for Oral Suspension
Nystatin Tablets

• Papaverine Hydrochloride Tablets
Penicillin, Phenoxymethyl
Penicillin, Phenoxymethyl, Capsules
Penicillin, Phenoxymethyl, for Oral Suspension
Penicillin, Phenoxymethyl, Tablets
Penicillin, Phenoxymethyl, Potassium
Penicillin, Phenoxymethyl, Potassium, Tablets
Pentobarbital Sodium Elixir
Pentobarbital Sodium Injection
Phenindamine Tartrate Syrup
Phytonadione Emulsion, Sterile
Phytonadione Tablets
Pipevazine Citrate
Piperazine Citrate Syrup
Piperazine Citrate Tablets
Piperocaine HCl Ophthalmic Ointment
Plasma, Antihemophilic Human
Poliomyelitis Vaccine
Polymyxin B Sulfate Ointment
Prednisolone Acetate
Primidone
Primidone Tablets
Probenecid
Probenecid Tablets
Prochlorperazine Ethanedisulfonate
Prochlorperazine Ethanedisulfonate Injection
Prochlorperazine Ethanedisulfonate Syrup
Prochlorperazine Maleate
Prochlorperazine Maleate Tablets
Progesterone Tablets
Promethazine Hydrochloride
Promethazine Hydrochloride Injection
Promethazine Hydrochloride Syrup
Promethazine Hydrochloride Tablets
Propantheline Bromide
Propantheline Bromide Tablets
Propylidone
Propylidone Suspension, Sterile
Propylidone Suspension, Oil, Sterile
Protamine Sulfate Injection
Pyridostigmine Bromide
Pyridostigmine Bromide Tablets
Pyridoxine Hydrochloride Injection
Pyridoxine Hydrochloride Tablets
Pyrimethamine
Pyrimethamine Tablets

• Radiocyanocobalamin Solution
Radiogold Solution

• Saccharin Calcium
Scopolamine Hydrobromide Injection
Secobarbital
Secobarbital Elixir
Selenium Sulfide
Selenium Sulfide Detergent Suspension
Sodium Carboxymethylcellulose Tablets
Sodium Diatrizoate Injection
Sodium Digoxin Injection
Sodium Glucosulfone Injection
Sodium Levothyroxine
Sodium Levothyroxine Tablets
Sodium Liothyronine

Dr. SMITH. The latest issue. I am sorry that the reproduction is of such a nature that you cannot read the names. But if it were closer, I believe it would be possible for you to follow my point, that many of these names cannot be reduced very easily to an understandable language, other than for chemists, pharmacologists, and those who are particularly conversant with drug structure. This is not by way of criticism. Instead, this is by way of a compliment paid to the men who work with the U.S. Pharmacopeia and the International Pharmacopeia, which has the same problem, because these men are determined to reveal, through a generic name, if possible, the chemical identity of the substance. And chemical names being what they are today, with our modern chemotherapy advances, they just pose real problems in nomenclature.

So this is entered into the record merely to emphasize that sometimes it is impossible to do some of the things that some have urged, so far as the general use of generic names is concerned.

The next four charts, 9, 10, 11, and 12——

Senator KEFAUVER. We will make those Nos. 273, 274, 275, and 276.

(Exhibits Nos. 273, 274, 275, and 276 follow:)

EXHIBIT 273

Arthralgia

A.P.C. w/Demerol (Winthrop) p 881
Algoson (McNeil) p 726
Alprine (Ulmer) p 851
Amadil Tablets (Breon) p 635
Anodynos-DHC Tablets (Breon) p 635
Aquadiol (National Drug) p 747
Armyl (Armour) p 619
Arthropan Liquid (Purdue Frederick) p 778
Aspir-B (Walker, Corp.) p 869
Aspirin Supprettes Preparations (Webster) p 876
Asteric (Brewer) p 642
Banesin Forte Tablets (Kendall) p 687
Calurin Tablets (Smith-Dorsey) p 813
Causalin Tablets (Amfre-Grant) p 617
Cibalgine (Ciba) p 654
Codempiral (B. W. & Co.) p 645
Daprisal (Smith Kline & French) p 817
Darvon (Lilly) p 708
Darvon Compound (Lilly) p 708
Demerol Compound (Breon) p 636
Demerol Hydrochloride (Breon) p 636
Demerol Hydrochloride (Winthrop) p 882
Demerol-APAP (Breon) p 636
Disipal (Riker) p 783
Donnagesic Extentabs (Robins) p 785
Drocogesic No. 3 (Carrtone) p 650
Ecotrin (Smith Kline & French) p 818
Edrisal (Smith Kline & French) p 818
Empirin Compound, Tabloid (B. W. & Co.) p 646
Empirin Compound w/Codeine Phosphate Nos. 3 & 4 Tabloid (B. W. & Co.) p 646
Epsilan-M Capsules (Warren-Teed) p 875
Ertron (Whittier) p 880
Felsol Powders & Tablets (American Felsol) p 615
Flexilon (McNeil) p 727
Flexin (McNeil) p 728
Guaiagesic (Columbus Pharmacal) p 661
Hasacode (Haskell) p 682
Hasamal (Haskell) p 682
Ischialgina Ampuls-Zambeletti (Italian Drugs) p 685
Leritine (Merck Sharp & Dohme) p 738
Lethopherol (Nutrition Control) p 753
Levo-Dromoran (Roche) p 790
Mephosal (Crookes-Barnes) p 663
Meprospan (Wallace) p 870
Meprotabs (Wallace) p 870
Miltown (Wallace) p 870
Monacet Compound (Rexall) p 782
Myoflex Creme (Topical Analgesic) (Warren-Teed) p 875
Narone (Ulmer) p 852
Neocylone (Central Pharmacal) p 650
Pabalate (Robins) p 786
Pabalate—HC Tablets (Robbins) p 786
Pabalate-Sodium Free (Robbins) p 786
Pabirin Preparations (Smith-Dorsey) p 814
Panac (Brewer) p 642
Panalgesic (Poythress) p 777
Pantopon (Roche) p 792
Paraflex (McNeil) p 728
Parafon (McNeil) p 728
Parafon w/Codeine (McNeil) p 729
P-B-Sal-C (Ulmer) p 852
P-B-Sal-C w/Esoprine (Ulmer) p 852
Percobarb & Percobarb-Demi Capsules Endo) p 673
Percodan & Percodan-Demi Tablets (Endo) p 673
Phenaphen Preparations (Robins) p 786
Polygesic (Arnar-Stone) p 623
Prednyl (U.S. Vitamin & Pharm. Corp.) p 851
Prolaire (Stuart) p 842
Pydirone (Breon) p 641
Pyralgin (Savage) p 803
Robaxin Injectable (Robins) p 787
Robaxin Tablets (Robins) p 787
Salcedrox (Massengill) p 726
Sal-Phenesin (Marion) p 724
Sodium Salicylate, Enseals (Lilly) p 716
Sylapar—H. C. Entells (Buffington's) p 644
Synalgos Preparations (Ives-Cameron) p 686
Synex & Synex-SA Capsules (Philadelphia Ampoule) p 773
Thru (Rexall) p 783
Tolyphy (Chicago Pharmacal) p 652
Trigesic (Squibb) p 838
Zactane (Wyeth) p 892
Zactirin (Wyeth) p 892

Arthralgia (Menopausal)
(see under Arthralgia)

Arthritis (Gonorrheal)
see under Infections (Gram-Positive & Gram-Negative Organisms)

Coronary Vasodilators

Aminet Suppositories (Ames) p 616
Aminoform Suppositories (Testagar)
Aminophyllin (Searle)
Aminophyllin Injection (Carrtone)
Aminophylline (Zemmer)
Aminophylline Injection & Tablets (Philadelphia Ampoule)
Aminophylline Preparations (Rexall)
Amitrate Tablets (Kremers-Urban)
Ammivin (Pure Khellin or Visammin, Tablets) (National Drug)
Amyl Nitrite Aspirols (Lilly)
Angitab (Moore)
Angitet (Harvey)
Antime (Carrtone) p 649
Antime Forte (Carrtone)
Aqualin Supprettes (Webster) p 876
Arazem (Zemmer)
Burrizem (Zemmer)
Cardilate (B. W. & Co.) p 645
Cartrax (Roerig) p 796
Choledyl (Warner-Chilcott) p 872
Corovas Tymcaps (Amfre-Grant) p 617
Diatraegus Pillets (Buffington's)
Duotrate Preparations (Marion) p 723
Equanitrate (Wyeth) p 886
Glucophylline Preparations (Abbott)
Glytheonate, Preparations (Smith, Miller & Patch)
Hespercone w/Vitamin C Capsules (Testagar)
Hyper-Zem (Zemmer)
Khelisem Tablets (Massengill)
Mannitol Hexanitrate w/Phenobarbital Tablets (Warren-Teed)
Metamine Preparations (Leeming) p 704
Miltrate (Wallace) p 871
Myocardone, Tablets (Chemico)
Natrona Comp. (Zemmer)
Neo-Corovas Tymcaps (Amfre-Grant) p 618
Neopavrin (Savage) p 803
Nipent Tablets (Moore)
Nitralox (Smith-Dorsey)
Nitraphyl (Ascher)

Nitretamin (Squibb) p 832
Nitroglycerin, Tablets & Hypodermic Tablets (Lilly)
Nitroglyn (Key) p 688
Nitrol Ointment (Kremers-Urban) p 690
Nitrol Tablets (Kremers-Urban) p 691
Nitrovas Tablets (Amfre-Grant) p 618
Papavatral L.A. (Kenwood) p 688
Papaverine Hydrochloride (Lilly) p 714
Paveril Phosphate (Lilly) p 714
Penite Tablets (Carnrick, G. W.) p 649
Pemophyllin Tablets (Pitman-Moore)
Pentaerythritol Tetranitrate Tablets (Philadelphia Ampoule)
Pentafort Capsules (Sutliff & Case) p 844
Pentoxylon (Riker) p 784
Pentraline (McNeil) p 729
Pentrol T.D. (Organd)
Pentrol, Tablets (Organd)
Peribar & Peribar LA Tablets (Whittier) p 881
Peritrate (Warner-Chilcott) p 873
Peritrate w/Nitroglycerin (Warner-Chilcott) p 873
Peritrate w/Phenobarbital (Warner-Chilcott) p 874
Peritrate Sustained Action (Warner-Chilcott) p 874
Perivas Tablets (Amfre-Grant)
Phenobarb, Theocalcin (Knoll) p 689
Rith-A-Tal (Walker, Corp)
Roniacol w/Aminophylline (Roche) p 793
Ruhexatal w/Reserpine Tablets (Lemmon) p 704
Ruphyllin (Searle)
Rutaminal Preparations (SchenLabs) p 804
Spasmalgin (Roche)
Synate (Central Pharmacal) p 651
Synophedal (Central Pharmacal) p 650
Synophylate (Central Pharmacal) p 650
Syntrate (Central Pharmacal)
T C S Tablets (Poythress) p 777
Tensodin (Knoll) p 690
Tetrasule & Tetrasule - S (Timesule) (Storck) p 840
Thaverine Tablets (Pitman-Moore)
Theobarb Preparations (VanPelt & Brown)
Theobarb-R (VanPelt & Brown) p 868
Theocalcin (Knoll) p 690
Theocardone (Haack)
Theoglycinate (Brayten) p 634
Theorate (Robins)
Theo-Tan (Organd)
Thesodate (Brewer) p 642
Tosec (Haack)
Unitroxin (Tilden)
Vasorutin (Buffington's)
Verina Preparations (Testagar)
Veruphen (Zemmer)
Xancylate Tablets (Pitman-Moore)
Xaniophen Tablets (Pitman-Moore)

Hypotensives

Abten Tablets (Maney)
Ademol (Squibb) p 824
Alfolia (Mallard)
Aminotal (Mallard)
Amite (Mallard)
Amvero (Mallard)
Angitab (Moore)
Ansolysen (Wyeth) p 884
Antime (Carrtone) p 649
Apresoline hydrochloride (Ciba) p 653
Arazem (Zemmer)
Arfonad (Roche)
Banasil (Ulmer)
Besertal (Central Pharmacal)
Binitrin Tablets (Vale)
Binitrin w/Butabarbital Sodium Tablets (Vale)
Burrizem (Zemmer)
Butiserpine (McNeil) p 727
Cardilate (B. W. & Co.) p 645
Carr-Serp Tablets (Carrtone)
Crataganite (Smith, Miller & Patch)
Crystoserpine (Smith-Dorsey)
Detensin Tablets (Philadelphia Ampoule)
Diatraegus Pillets (Buffington's)
Diupres (Merck Sharp & Dohme) p 735
Diurbital Tablets (Amfre-Grant) p 617
Diuril (Merck Sharp & Dohme) p 735
Elserpine-Prab (Canright) p 648
Equalysen (Wyeth) p 885
Eskaserp Spansule (Smith Kline & French) p 818
Ethased (Mallard)
Ethavex (Mallard)
Exidrix (Ciba) p 655
HBP (Saron)
Haimased (Tilden) p 847
Harmonyl (Abbott) p 606
Harmonyl-N Filmtabs (Abbott) p 607
Hep-Nine B Fortis (Columbus Pharmacal) p 661
Hespercone w/Vitamin C Capsules (Testagar)
Hexaflavinal Tablets (Testagar)
Hexamethonium Chloride Tablets (Panray)
Hydergine (Sandoz) p 802
HydroDIURIL (Merck Sharp & Dohme) p 737
Hydropres (Merck Sharp & Dohme) p 737
Hyperloid Preparations (Person & Covey) p 766
Hyper-Viscra (Lloyd Brothers)
Hyper-VV Tablets (Moore) p 747
Hyper-Zem (Zemmer)
Hyserp Injection (Moore)
Hyserp Tablets (Moore)
Hyserpin Tablets #1 and #2 (Physicians Products)
Inositol Hexanitrate Tablets (Panray)
Inversine (Merck Sharp & Dohme) p 738
Ironyl (Physiological) p 774
Koglucoid Tablets (Panray)
Lemiserp 0.1 mg. & 0.25 mg. Tablets (Lemmon)
Loten Tablets (Maney)
Malrused (Mallard)
Maltrate w/Phenobarbital (Mallard)
Manniphen, Tablets (Vale)
Manniphen w/Rutin, Tablets (Vale)
Mannitol Hexanitrate Tablets (Panray)
Mantrin Tablets (Tilden)
Maxitate (Strasenburgh) p 840
Medomin (Geigy) p 678
Mepherin (Harvey)
Mio-Pressin (Smith Kline & French) p 819
Moderil (Pfizer) p 769
Natrinil Powder (National Drug)
Natrona Comp. (Zemmer)
Neo-Protapine (Durst)
Neothylline (Maney) p 723
Neozyme Tablets (Barrows)
Nibarb Tablets (Breon) p 640
Nidar (Armour) p 621
Nipent Tablets (Moore)
Nitranitol Preparations (Merrell) p 744
Nitraphyl (Ascher)
Nitrillin Tablets (Maney)

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Nitroglyn (Key) p 688
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Dr. SMITH. There is no point in studying each separately. They are all about the same. They are what you might call blowups from pages of "Physicians Desk Reference," a book made available by a publishing house for physicians, which indicate the variety of substances that are available for given conditions, the given conditions being the boldfaced type at the top, the variety of substances, and the firms making them available in the lighter faced type.

The next exhibit is one that I show to you with an explanation. It does not lend itself as an exhibit without oral description, although the accompanying reprint does, for the record.

Two or three years ago, the AMA Chemical Laboratory was deeply concerned because of poisonings that occurred from time to time with patients and children. Physicians, pharmacists, and members of health departments and toxologists in general were hard pressed to quickly identify these compounds, or these pills or tablets, so that prompt corrective measures could be instituted. So the chemical laboratory devised a scheme for permitting recognition of substances by their appearance, this depending on whether they are round or thick or concave or convex, what colors they are, what kind of a visual appearance there is when you cut them open, and so forth.

After examining several hundred of these, members of the laboratory staff came to the conclusion that it would be possible to devise a scheme for a quick identification of most pills and tablets. They consulted pharmacologists and pharmacists and toxocologists and physicians and drug manufacturers, and after further study concluded that that really could be done. As a result, they were able to publish in the Journal of the American Medical Association in January 1959, an article entitled "Identification Guide for Solid Dosage Forms."

Now, this becomes important, I believe, Mr. Senator, and gentlemen of the committee, because when one is dealing with a case of poisoning, time is very important. The chemical laboratory, by using the very tricks of the trade of the drug industry—that is, by identifying brands in certain ways, has worked to the benefit of people who are poisoned; and, obviously, to the benefit of those who are trying to promote a quick recovery.

So it would seem to me that sometimes when we consider what me might call business practices, we should take into consideration many more factors than become apparent during the earlier discussions.

In charts Nos. 13 and 14—13, first, it is possible to see——

Senator KEFAUVER. That will be exhibit 277.

(Exhibit No. 277 follows:)

Delivery time,[1] drug order

Delivery of Los Angeles order to Detroit manufacturer	days	3
Clerk opens order	minute	1
Sent to sales department	minutes	5
Priced by sales department	do	2
Sent to distribution department	do	5
Distribution manager handles order	do	2
Prepare invoice	do	4
Sent to stock department	do	5
Picker fills order	do	1½
Stock checker checks accuracy	do	1½
Wrapper prepares for mail	do	4
Sent to truck	do	2
Total	do	33
Delivery of drug from Detroit manufacturer to Los Angeles	days	3

[1] Excludes pharmacist's professional time.

Dr. SMITH. Thank you, sir.

In chart No. 13, it is possible to see how much time would elapse if a pharmacist did not have a brand available in his drugstore, and he had to submit an order to a distant city. This was a study made by a newspaper, a member of the Hearst organization. It involved a pharmaceutical house in Detroit, and a pharmacy in Los Angeles. And someone actually clocked the number of steps involved, the time involved, and this, you see, adds up to a period of almost a week. And this excludes the pharmacist's professional time; a period of a week from the time the order is placed until the pharmacist gets it in the hands of the firm, and then has it returned.

Now, the next chart shows what happens when the brand is immediately available. The pharmacist takes the message——

Senator KEFAUVER. This will be exhibit 278.

(Exhibit No. 278 follows:)

Delivery time,[1] drug order

	Minutes
Delivery of Los Angeles prescription to Los Angeles pharmacist	15
Remove package from storage	1
Wrap package	1
Delivery of prescription to patient	17

[1] Excludes pharmacist's professional time.

Dr. SMITH. The pharmacist takes the message, he turns to the shelf behind him, or a convenient place of storage and removes the requested article. There is a period of 17 minutes as compared to

almost a week. This, too, excludes the pharmacist's professional time, as it did in both cases, as he assesses the prescription and exercises certain precautionary measures in compounding that often must go with the issuance of a prescription.

The next bit of discussion on this trade names versus generic names situation can be briefly summarized, and this is all that I would have to say, Mr. Chairman, at this time about it.

I think that I can say that the members of the Pharmaceutical Manufacturers Association have no dispute with the use of generic names. Physicians have been able to use generic names for years. The PMA members do, however, have a deep concern with quality. They are much concerned with the kind of preparation that they make available, or that others in their field make available. And so many of these manufacturers put the reliability and the integrity associated with their names on the line, so to speak, when they promote a brand name in connection with a product, because that reflects the controls, the thought, the research, that goes behind it, so far as those firms are concerned. So the question is of quality, and guarantee of quality—a matter of deep significance to the practitioner and to the public, as well as to the members of the Pharmaceutical Manufacturers Association.

Textbook descriptions will reveal the importance of these variations, even minor ones. I have, but would not at this time introduce for your record since it probably already is voluminous, information which shows variations that occur even with the U.S.P. preparations. Now, this does not indicate that the U.S.P. is lacking. It merely indicates that with permissible standards, it is possible to have considerable variation, if one wants to cut the corners sharply.

Senator KEFAUVER. Is the function of the National Pharmaceutical Council largely to promote trade names rather than generic names?

Dr. SMITH. I don't know anything about it. I am not a member of its board, or anything.

Senator KEFAUVER. The 20 companies are all members of your association, are they not?

Dr. SMITH. I don't know that even. I don't even know the membership of NPC.

Senator KEFAUVER. Are you aware of their work?

Dr. SMITH. I know a little bit about their work; yes.

Senator KEFAUVER. Is that one of the chief functions of the National Pharmaceutical Council?

Dr. SMITH. That I cannot say.

Mr. WORLEY. I think they are primarily engaged in preventing substitution. When there is a certain item prescribed in a prescription, and unlawfully the pharmacist substitutes something else, I think that is their principal engagement. I am not familiar with it, either, Mr. Chairman.

Senator KEFAUVER. A trade name avoids substitution; is that correct?

Dr. SMITH. I have a list of membership——

Senator KEFAUVER. That is true; is it not? A trade name avoids substitution? That is the purpose of the National Pharmaceutical Council?

Mr. WORLEY. I am not familiar with that.

Dr. SMITH. I think an officer ought to answer that one.

Senator KEFAUVER. Who are the members of the National Pharmaceutical Council?

Dr. SMITH. A booklet was just given to me, which was printed in 1957. It is the only one that I have. It lists— Do you want me to read the names in 1957?

Senator KEFAUVER. Yes, sir.

Dr. SMITH. Abbott Laboratories, Ames Co., Inc.; Burroughs Wellcome & Co. (U.S.A.) Inc.; CIBA Pharmaceutical Products, Inc.; Geigy Pharmaceuticals (division of Geigy Chemical Corp.); Hoffmann-La Roche, Inc.; Lederle Laboratories (division of American Cyanamid Co.); McNeil Laboratories, Inc.; Mead Johnson & Co.; Merck Sharp & Dohme, division of Merck & Co., Inc.; the William S. Merrell Co.; Ortho Pharmaceutical Corp.; Pitman-Moore Co. (division of Allied Laboratories, Inc.); J. B. Roerig & Co. (division of Chas. Pfizer & Co., Inc.; G. D. Searle & Co.; Smith Kline & French Laboratories; E. R. Squibb & Sons (division of Olin Mathieson Chemical Corp.); the Upjohn Co.; Warner-Chilcott Laboratories; White Laboratories, Inc.; Winthrop Laboratories (division of Sterling Drug Inc.); Wyeth Laboratories (division of American Home Products Corp.).

Senator KEFAUVER. Are they all members of your association, the Pharmaceutical Manufacturers Association?

Dr. SMITH. These all are, with the exception of one, which is a division of a firm that is a member of the PMA.

Senator HRUSKA. Mr. Chairman, could the witness identify the book from which he is reading?

Mr. WORLEY. This has just been handed to us. It is entitled "24 Reasons Why Prescription Brand Names Are Important to You."

Senator HRUSKA. Maybe it might be well to put it in the record, Mr. Chairman. So we can study it in our leisure.

Senator KEFAUVER. I am advised it is already in the record.

Senator HRUSKA. As an exhibit, or is it part of the record?

Senator KEFAUVER. As an exhibit.

(The exhibit referred to may be found in pt. 15, p. 8637.)

Senator KEFAUVER. I was wondering about that, because I have a letter here which indicates that PMA and the National Pharmaceutical Council work fairly close together. This letter came to us as an exhibit. I think I might read the letter and ask you about it.

This is from the Upjohn Co., dated November 18, 1959, addressed to Mr. Carl K. Raiser, assistant to the president, Smith Kline & French Laboratories. It is signed by J. W. Schma, assistant director, domestic branch sales of Upjohn.

It says:

DEAR CARL: I recently read your contribution to the September SPEA Pharmaceutical News and want to say I believe you have put your finger on a very weak link in our PR chain of communications—the inarticulate pharmacist.

While I don't question that the very excellent PR firm retained by the PMA will do the best possible job in a direct way with the consumer, I feel the National Pharmaceutical Council and its members should continue to put words into the mouth of the pharmacist at every opportunity so that helpful answers, not damaging ones, can be made to questions concerning the pricing of prescriptions.

Kindest regards.

(Signed) J. W. SCHMA.

Your association is mentioned in this letter. What do you think about that, Dr. Smith?

Dr. SMITH. I have no knowledge of this letter. I don't know why they should mention PMA. This is a letter signed by a representative of a firm. And it seems to me that it is solely the responsibility of either the employee or the firm or the management of the firm, and not PMA. I wouldn't have any reason to see this.

Senator KEFAUVER. The reason I ask you about it is that he says that through your excellent public relations firm—I guess that is Hill & Knowlton—you are doing the best job possible in a direct way with the consumer, but that he feels that the National Pharmaceutical Council ought to put words into the mouth of the pharmacist, so that they would have helpful answers and not damaging ones to questions concerning the price of the prescription.

I therefore wondered if there was teamwork, or if you were working together, in connection with your effort toward the consumer, and their effort toward putting words into the mouth of the pharmacist.

Dr. SMITH. We have no cooperation with them at all, PMA-wise. We have no joint committees. Hill & Knowlton, the firm retained by PMA, is only to promote good medical care in the field of drug medication, and the related things that go with it. It has nothing to do with MPC. It seems to me what is developing now is kind of a reflection in some way on pharmacy. I wonder if pharmacists should not be asked to comment.

Senator KEFAUVER. You were mentioned in this letter, and I thought, while you were here, would be the time to ask you about it.

Dr. SMITH. That isn't even free advertising, sir. We didn't know anything about it.

Senator KEFAUVER. The members of your association are the members of this council, so I thought I would ask you about it.

Senator HRUSKA. Mr. Chairman, in view of the fact that the letter has been read, would it not be well to call in the writer of the letter so he can explain it, in fairness to him?

Senator KEFAUVER. The Upjohn people will be here next week. And, of course, if in the meantime they want to make any comment about it, they can do so.

Senator HRUSKA. They can't make a comment unless they are notified. Will steps be taken so they can get a copy of the letter and contact the writer?

Senator KEFAUVER. We will certainly do so. But the letter came to us from Smith Kline & French, though it was written by Upjohn. We will certainly notify them.

But, in that connection, referring to putting words into the mouth of the pharmacist, and also your direct effort to convince the consumer, I have something I think should be made a part of the record. It is very brief. It is an article from the West Coast Druggist, for January 1960. The second headline says, "Here's How To Counteract Effects of Kefauver Hearings in Your Area." All of the article will be made a part of the record as exhibit 279.

(Exhibit No. 279 may be found on p. 10964.)

Senator KEFAUVER. It includes a sample press release with the name of the pharmacist to be filled in, so that it can be sent to a newspaper. It says:

Here is the procedure to follow to insure publication of these releases in your local newspaper: 1. Retype the press release on a sheet of white paper, double spacing the copy. If you cannot retype the story, just cut out the box at the right and use it as it is. It is far better, however, that the story be completely retyped as already described.

2. Fill in your name in the blank spaces provided. Use your full name in the first paragraph; and, thereafter, only your last name.

3. Handcarry the release to your local newspaper editor. (If you haven't the time to take it to the newspaper office, you can mail it; but this is far less effective in insuring publication.)

If you will retype the release and deliver it personally to the newspaper editor, the chances of its being printed are fairly good because it carries the weight of a local story and quotes a local source.

Most weekly papers have only one "editor." He is the man to see. Daily newspapers have a number of "editors" and the best one to see on a daily is the "city editor," or his assistant.

If you know the "chief editor" of your daily newspaper personally, by all means drop by to see him. But, give the news release to the "city editor." He is the man responsible for local news and he may be displeased if he thinks you went over his head.

Then, following exhibit 279, is a news story typical of several articles we have received. This will be exhibit 280.

(Exhibit No. 280 may be found on p. 10965.)

Senator KEFAUVER. This is from the Westlake Times, dated Wednesday, February 3, 1960. In it this suggested news release is printed word for word with the name of the pharmacist filled in. So this was effective.

Do you know anything about this?

Dr. SMITH. No. Who sponsored that which appeared in the West Coast Pharmacist? This is news to me.

Senator KEFAUVER. I was just asking you about it.

Dr. SMITH. I don't know. Not PMA.

Senator KEFAUVER. Does Hill and Knowlton have anything to do with this?

Dr. SMITH. Not that I know of. They are only supposed to do things with direction from PMA in this respect.

Senator KEFAUVER. Will you inquire?

Dr. SMITH. Now or later, sir?

Senator KEFAUVER. Later on, and advise us about it?

Dr. SMITH. All right.

(The information referred to may be found on p. 10991.)

Senator DIRKSEN. Well, Mr. Chairman, I would like to make a little comment. I don't know anything about the West Coast Druggist or its pharmacy journal. It is quite evident, of course, they are learning some techniques from Senate committees of how to get on the front page, for one thing. By Jove, I am glad for some vigor in this matter. I said before, and I reaffirm, there have been so many misleading things go out of this committee that I thought it was a shame, and I have had no hesitation in saying so. And I am just glad that one of these trade associations or groups gets up on its hind legs, and undertakes to tell the other side of the story.

Senator KEFAUVER. I am sure Senator Dirksen doesn't endorse this kind of canned stuff.

Senator DIRKSEN. How much canned stuff is sent out from here? Go downstairs and see the mail bags of stuff reprinted from the Con-

gressional Record that goes out. If that isn't canned stuff, I don't know.

Senator KEFAUVER. But the difference, I think, Senator Dirksen, is that what we prepare here we do ourselves. We at least contribute to the source. But in this case some public relations firm or somebody else is getting published in these magazines and newspapers stories that they want the pharmacies to present as their own.

Senator DIRKSEN. Well, what about the press release this committee has been issuing? I have no part of it, except those I have editored myself.

Senator KEFAUVER. We try to issue press releases that are meaningful, and at least they are attributed to me. I am responsible for them. I do think in the case of canned material like this, we ought to know where it is coming from—whether it is Hill & Knowlton, whether it is the National Pharmaceutical Council, whether it is somebody else. We want to find out who issued it.

Senator DIRKSEN. Well, if they want to instruct them how to get up a release and go see the editor, what is wrong with it?

Dr. SMITH. Well, apart from that, sir, I would just say that Pharmacy acts independently of the Pharmaceutical Manufacturers' Association, as does Medicine. Where we have a crossover of interest in medical care we obviously meet that challenge. But I have no way of knowing of any relationship with any group of west coast pharmacists. Certainly it is not with PMA.

Senator KEFAUVER. You make inquiry about it, Dr. Smith.

Dr. SMITH. I would be glad to do so, sir.

Senator HRUSKA. Mr. Chairman, just by way of another incidental remark, I should think we ought to concern ourselves with the truth and merit of the disclosures of this release, more than its source. I don't know. Maybe the chairman wants to take exception to some of the statements made in the press release. Is that the chairman's idea? Is there something evil or dishonest in it?

Senator KEFAUVER. The whole press release has been made a part of the record. I want to bring out that this is apparently an effort to have the druggists distribute something that he didn't prepare himself, and have him just add his name to something that is furnished to him already and to put it out as his own story, with the purpose to deceive, or at least to some extent mislead, the newspaper editors. The druggists are asked to accept this as their own story, and to type it themselves. But it is apparent that it is not their own story; it is something that has been sent to them for them to try to give to the newspaper editor as their own story. I don't think that is a very fair way of trying to get the news to the public or to the editors.

Dr. SMITH. Mr. Chairman, I cannot speak for pharmacy, but I think I should say in deference to men who are dedicated to the promotion of health in this country, as represented certainly in the American Pharmaceutical Association, in its April 1960 issue, of its official journal, there is a story about the presentations before this subcommittee, and there are both sides of the story. In fact, your picture and Dr. Blair's are on the cover.

There are two or three others here.

Senator KEFAUVER. Yes, we have a copy of that issue. Later on we will ask you some questions about it.

Dr. SMITH. All right.

Senator KEFAUVER. All right, sir, you may proceed.

Dr. SMITH. I have another comment on the generic versus trade names question to emphasize that the members of the Pharmaceutical Manufacturers Association are interested in quality. And incidentally, I assume, Mr. Chairman, in deference to trying to save time for the subcommittee, that I have blanket permission to insert in the record the statements which I have abbreviated.

Senator KEFAUVER. If you will tell us where you want to insert them, we can make them exhibits.

Dr. SMITH. All right, sir. To refer to an experience in Canada——

Senator KEFAUVER. Is there some statement you want to put in the record now?

Dr. SMITH. No, I will summarize this. The transcript will be sufficient.

I mentioned a few moments ago that the PMA members are much concerned about quality, and guaranteed usefulness of the substances that are made available in this country. Just to show that this problem can occur elsewhere, I would like to refer to an experience in Canada, which was reported by a representative up there a short time ago. I will quote very briefly from a Canadian study, which shows the results of lack of control based on Canadian standards, and they are comparable to American standards.

A hospital received chloramphenicol below strength, but the seller refused to accept the return of the product.

A hospital has had several instances of products being excreted without disintegration.

A pharmacy states definitely that many products are under strength.

In a hospital purchase of phenolbutazone, the outer coating falls off on slight pressure.

Another hospital bought sodium sulphacetamide in an ophthalmological ointment, that darkened rapidly, and the pharmacists had to squeeze the tubes until a clear or white ointment was found, and thus wastage was high.

Another hospital bought tablets of aluminum hydroxide; thousands were discarded due to poor taste, therapeutically ineffectiveness. This stresses the need, I believe, for the careful controls being exercised by the responsible element of the pharmaceutical industry. And the PMA members are determined to meet their obligations in this respect.

Senator KEFAUVER. Dr. Smith, I think you conceded last time that quality control is not the exclusive practice of large companies. Many small pharmaceutical manufacturers have just as effective quality controls as larger ones, and in some cases some of the larger ones have not done too well for their quality control on some occasions.

Dr. SMITH. Well, we were not talking, sir, about large versus small. There are large and small members of PMA. We are talking about adequate controls versus poor controls.

In this connection, may I just, in conclusion, draw your attention to a study that was made by us on FDA legal actions involving PMA members and non-PMA members between 1950 and 1959. Now, all of these were civil seizure actions, except two criminal cases, one in 1954 and one in 1956.

The non-PMA members for 1953–59 had actions, total actions against them, ranging from 139 to 203 per year.

The PMA members, who believe in research and control—the large and small firms that are members, during those years had from 6 to 10 cases perhaps, sometimes less. Here is one year with four, another one with four. Some of these involved disputes, not over poor products, but over whether or not the firm had the right, for example, to confine its preparations to a prescription legend.

Senator KEFAUVER. You are making this part of the record?

Dr. SMITH. I will.

Senator KEFAUVER. We will make that exhibit 281.

(Exhibit No. 281 may be found on p. 10966.)

Dr. SMITH. Now, Mr. Chairman, I have presented this additional material. I have other material to which I would refer, if you wish me to, from time to time, during questioning. I would like to express appreciation to all the members of the subcommittee for their patience and understanding.

Senator KEFAUVER. Very well. Thank you very much, Dr. Smith.

Senator HRUSKA. Mr. Chairman, has the entire statement of the witness been included in the record?

Senator KEFAUVER. Dr. Smith's prepared statement of this morning was all put in the record. He summarized parts of it, but the rest is included in the record.

Senator HRUSKA. It has six parts, I understand.

Senator KEFAUVER. Yes, all of it will be put in the record.

The first part of his statement related to concentration of competition, and I think we might try to get some of these matters cleared up now.

When you were here in February, Dr. Smith, it was called to my attention that a press release was put out criticizing the concentration chart which had been prepared by the economic staff under Dr. Blair. It was your press release of February 24. So it was suggested that Dr. Blair get up a more complete statement in connection with the concentration chart which you criticized in your February press release and in the first part of your statement here today.

We have a memorandum from Dr. Blair in connection with it, which we will make exhibit 282. Without reading all of it, will you point out the high points of it, Dr. Blair?

(Exhibit No. 282 may be found on p. 10967.)

Dr. BLAIR. Mr. Chairman, in this memorandum, which I understand now has been made part of the record, I of course am addressing myself to the statements made by Dr. Smith in the course of the presentation, and also to statements made by the PMA in the press release to which you made reference of February 24.

In this memorandum, I wish to offer a few comments concerning the press release, and Dr. Smith's testimony on this issue.

I have four points to make, and I shall try to summarize them as quickly as possible.

First, the press release states:

> The Senators' staff has attempted to show with this chart that 16 companies control two-thirds of the 1958 dollar volume of prescription sales.

The PMA is in error. I made no statements of any kind concerning the degree of concentration in "prescription drug sales," or in

any such general category. The figures "16" and "two-thirds" were used in my presentation but in an entirely different context. They were employed to show the relative aggregate importance, in terms of the total value of all ethical drugs, of the individual drugs for which concentration ratios were individually shown in the table. The table presented concentration ratios individually for 51 products. These products, I pointed out, "represent at least two-thirds of the 1958 value of ethical drugs" (see p. 10777).

Senator KEFAUVER. I remember that distinctly. You said that the corticosteroids, tranquilizers, insulin, antibiotics, and I believe sulfa and vitamins, represented about two-thirds of the 1958 value of ethical drugs.

Dr. BLAIR (reading):

> Apparently the PMA has arrived at its erroneous conclusion by substituting "16" for "51" products in the sentence which ends "* * * represent at least two-thirds of the 1958 value * * *."

Having thus misstated my testimony the press release proceeds to contend that this level of concentration in "prescription drug sales" is lower than in other industries. Since the figure employed by the PMA is erroneous, the comparisons with other industries are meaningless.

2. The press release misstates the nature of the table by conveying the impression that what is presented is not the concentration of production of the drugs themselves but the concentration of "medicinal chemicals" which are employed as raw materials in the manufacture of drugs. The release states, "This chart shows, for example, that three firms produce all the bulk chemicals that go into a corticosteroid drug known as prednisolone." The table does not show the concentration of "bulk chemicals" that "go into" this or any other drug; it shows the concentration of production of prednisolone itself.

And this is true of the other drugs shown on the table.

All that is added to prednisolone before it is sold to the final customer is a very inexpensive inert material, which serves as a binder holding the product together when it is pressed into the form of a pill or tablet. There are bulk chemicals of one kind or another which do go into the various products shown on the table. Both of the oral diabetic drugs shown, Orinase and Diabanese, are manufactured from bulk chemicals known as isocyamates. The table does not show the concentration of production of isocyamates; it shows the concentration of production of Orinase and Diabanese.

3. The release implies that I ignored the fact that one product within a category, such as hormones, may compete with other products within that same category. It states, "Furthermore, the chart does not explain that prednisolone is a product that is itself competitive for prescription purposes with more than half a dozen corticosteroids." In my testimony I did note this fact and then went on to call attention to its limited significance, which I did on page 10780.

Further examination reveals that even after making full allowance for the possibilities of substituting one drug for another, the level of concentration is by any standard remarkably high.

In steroid hormones, of the nine products shown on the table the total output is accounted for by one company in the case of three, by two companies in two, and by three companies in the remaining

four. Dexamethasone, the largest selling product in this group with over 30 percent of the sales of all steroid hormones, is produced entirely by two companies, Merck and Schering, which with one other, Ciba, account for all of the sales. While it is true that the "predni" drugs are currently sold in bulk form to smaller companies, such sales will cease under contracts now in effect if the patent is awarded to any of the firms involved in the current interference proceedings, other than Syntex.

In diabetic drugs there are two principal producers of insulin—Lilly with 77 percent and the Squibb Division of Olin Mathieson with 19 percent. This is the concentration facing the majority of diabetic patients who cannot be transferred to the oral antidiabetic drugs. Those who can be placed on oral medication are virtually limited to two drugs, tolbutamide (Orinase) and chlorpropamide (Diabanese). A complete monopoly of sales of the former is held by Upjohn and of the latter by Pfizer.

Of the two types of tranquilizers, Smith Kline and French, with its Thorazine and Compazine, is dominant in the potent drugs, while Carter Products, with the meprobamate, has no close rival in the mild drugs. Smith Kline and French is the exclusive domestic licensee of Rhone-Poulenc, while Carter licenses only American Home Products.

Perhaps because of competition with rauwolfia serpentina, of which it is a derivative, or a lack of confidence in the patent, reserpine is sold in bulk or licensed to small drug companies by Ciba.

All of the nine sulfa drugs shown on the table are manufactured by only three firms—the Lederle Division of American Cyanamid, Hoffmann-LaRoche, and Merck. In eight of the nine products one or the other of these companies has a complete monopoly. In the case of only one, sulfathiazole, are there as many as two producers—American Cyanamid with 73 percent and Merck with 27 percent.

Of the nine vitamins shown, there are three produced exclusively by a single company (two by Merck and one by Hoffmann-LaRoche), while in three others Merck together with Hoffmann-LaRoche produces 100 percent of one, 89 percent of another, and 95 percent of the third. In still another Merck shares the entire output with Hoffmann-LaRoche and Pfizer. And the latter two firms account for 64 percent of the output of the eighth product. Only in the case of one vitamin, folic acid, are neither Merck nor Hoffmann-LaRoche among the principal producers, and here American Cyanamid produces 65 percent of the output.

Among the wide-range antibiotics shown the most important is tetracycline followed by chloramphenicol. Tetracycline is produced entirely by three companies, American Cyanamid, Bristol-Myers, and Pfizer, which together with Squibb and Upjohn, the only other sellers, have been proceeded against by the FTC on the grounds of having entered into a price-fixing conspiracy in the sale of this product. Parke Davis has a complete monopoly in both the production and sale of chloramphenicol.

Mr. Chairman, my final point, which I don't think I need take the time of the committee with at this point, concerns efforts by Dr. Smith to contradict the showings of the table by making reference to figures which were prepared originally for the National Industrial Confer-

ence Board by the Census Bureau, and then reworked by the Conference Board, and transmitted to Dr. Smith.

This is rather technical statistical material, and I would be perfectly content to stand on the memorandum as it exists on this point.

Senator KEFAUVER. All right. As I understand it, all these figures on production are taken from the records of the companies themselves?

Dr. BLAIR. The numerators are from the records of the companies themselves, supplied to the subcommittee in response to inquiries sent out by the subcommittee. The denominators are figures published by the Tariff Commission in the great majority of the cases, and in a few cases represent the total production for the product estimated by the subcommittee staff on the basis of returns submitted to us.

Senator KEFAUVER. Very well.

Senator DIRKSEN. Well, Dr. Smith, have you seen that statement before?

Dr. SMITH. No, I just read it, but I am still confused, because what we all were discussing, and perhaps this is because Dr. Blair and I are viewing it differently—but what I thought we were discussing, is competition among companies attempting to alleviate the suffering of mankind, and so therefore I would think in terms of number of companies selling products, and not number of companies producing. I think of it in the same way that say the Chevrolet firm produces all Chevrolets, whereas the dealers supply the cars to the people throughout the country.

So if one were to take this list of Dr. Blair's which is of producing companies, it would seem to me that there is nothing unusual here. They are the chemical producers. But the important thing is the attempt of the pharmaceutical manufacturers in this country to make available this material for those that need it, and there is no question in my mind, in the list that I have in front of me, that the number of companies providing the finished product indicate the keenest competition you could hope to have in any industry.

For hydrocortisone, for example, Dr. Blair says there are three producing companies. According to the latest information I have, there are 108 companies selling this material in finished form to pharamacists for their physicians prescriptions. And it seems to me that concentration of basic chemical production as a measure of competition is open at any time to considerable question. What we have to do is to think in terms of market—who meets the market, how, under what terms?

Senator KEFAUVER. Dr. Smith, as to the difference between those who manufacture a drug and those who sell it, in the case of automobiles our hearings concerned three or four companies. We did not attempt to include the thousands of dealers who sell automobiles. So that you can have no dispute with Dr. Blair's chart, because it is based on information that the companies sent to us and to the Tariff Commission, and it includes the companies which are producing these particular drugs mentioned here.

Dr. SMITH. No, I didn't say I didn't have any dispute, because I have not read Dr. Blair's memorandum yet. I would have to read it later, but he is talking about chemical producers. I am talking about drug producers.

Senator KEFAUVER. This is the same chart that you based your press release on.

Dr. SMITH. I would like to read that later.

Senator DIRKSEN. Well, Dr. Smith, since you have not seen this statement, and I have not seen Dr. Blair's statement before, I think if there is some comment you care to make, you could send it up in memorandum form, and I think that it should go into the record.

Senator KEFAUVER. There is no objection to that, of course.

Senator HRUSKA. Dr. Smith, may I ask—or Dr. Blair—is this chart to which we referred, is that a chart of the bulk production, or of the end production—of the end product as it is sold to the physician, or to the pharmacy, as the case may be?

Dr. BLAIR. This is the production of the product in the form in which it is reported to the Tariff Commission. Now in most cases, it is reported to the Tariff Commission in a form similar to that which I described in my memorandum with reference to prednisolone. That is to say, there needs to be added to the drug only some inert material to hold the drug together, as a binder, when it is pressed into the form of a pill or tablet. What is reported here again, I emphasize, is not the concentration of bulk chemicals out of which these drugs are manufactured. This is the concentration of the products of the drug industry.

Senator HRUSKA. Well, now, Dr. Blair, referring to the second paragraph of page 2a, the statement there is, after you point out that there are two principal producers of insulin, Lilly, with 77 percent and Squibb division with 19 percent, you go on to say, "This is the concentration facing the majority of diabetic patients who cannot be transferred to the oral antibiotic drugs."

Is it your idea that when a diabetic who uses nonoral drugs is limited to going into the drugstore and saying, "I want Lilly," or "I want Squibb," and that is all he can get by way of insulin which he is using?

Dr. BLAIR. Mr. Chairman, of course, he can also get insulin made by Merck, and there is also a specialized type of insulin marketed by Burroughs Wellcome. This does not amount to more than 1 or 2 percent of the total, but we do not have details on the production.

Senator HRUSKA. I am talking about the end product now, Doctor.

Dr. BLAIR. The end product is insulin, sir, and it is produced—it was produced in 1958 in its entirety by the three companies shown.

Senator HRUSKA. The end product I am talking about is the box that the patient ultimately uses. Is that what you want to say in that sense of Lilly or of Squibb? Is that what you want to say?

Dr. BLAIR. Lilly, Squibb, or a very small amount from this other company.

Senator HRUSKA. To those three companies alone.

Dr. BLAIR. Yes, in the United States.

Senator HRUSKA. That is your understanding?

Dr. SMITH. One other firm has a small amount. But insulin is an unusual case, and furthermore, the diabetic patient is not limited in the treatment of the disease to insulin. Many of the diabetic patients can be treated successfully by the oral antidiabetics. In the past years, as I recall it, there have been other insulin producers, but it was unnecessary for them to continue to produce to meet the existing demand.

I think that insulin is an unusual case. I would like to ask again, however, why we talk about chemical products when we should be discussing the finished products, because there is more than adding a binder to this material, and putting it out in pills or a capsule. The number of control steps that are necessary, the kind of excipient that you use, whether you use a sugar or no sugar, all of these things become important. In my previous testimony, I mentioned the hundreds of thousand of dollars that must go into the development of the control procedures. I have exhibits over here which show what is involved, but I refrained from showing them to you this time because of lack of time.

But it is the chemical production you are discussing, not the finished product that is going into a capsule for the patient.

Mr. DIXON. Dr. Smith, it is the material that is in the finished product from which the medicinal benefit comes; is it not?

Dr. SMITH. To the same extent that steel is in a car, yes.

Mr. DIXON. No, I would not agree with you on that. I think if you reflect, that you won't. In other words, as an example, Upjohn produces 45 percent of prednisolone, as reported to the Tariff Commission, and to the subcommittee. That is finished bulk prednisolone. It is that finished product which is then transmitted into a tablet by some process. As it has been described to us heretofore at great length by witnesses, putting it in finished form does entail controlled processes.

Senator KEFAUVER. I think we all understand that.

Very well, let's proceed.

Dr. BLAIR. Mr. Chairman, the second part of Dr. Austin Smith's statement, which begins on page 6 of his excerpts, concerns a study by the American Telegraph & Telephone Co. entitled "Profit, Performance, and Progress." I only have a brief comment to make upon what I presume are intended to be the economic implications of this report, which I hasten to add I have never seen. I see it bears a date May 1959.

Senator KEFAUVER. Is that the A.T. & T. report we are talking about here?

Dr. BLAIR. Yes, sir. My comment is very brief. I just wish to point out that the economic profession will be gratified to learn that "the very concept of economists that competition must be thought of in terms of price alone" has been proved to be "erroneous."

Interestingly, this contribution to knowledge has been made by the world's largest private monopoly, the American Telegraph & Telephone Co. It is, of course, true that there are other forms of rivalry than price, such as service and quality. The stress placed by economists on price, however, is due to the belief that what is termed in the economic profession the elasticity of demand for a product is generally lower for these other forms of rivalry, assuming that they could be quantified, than for price. For example, would the market for automobiles in the first quarter of this century have expanded as it did if price, instead of declining sharply, as it did, had remained stable, and quality and service had been improved ad infinitum?

Senator KEFAUVER. The next part of Dr. Smith's statement refers to "Discovery and Development."

I want to say in that connection that so far as I am concerned, and I am sure so far as this committee is concerned, there is no inclination or no desire to take away any credit from any American pharmaceutical manufacturer, or from the industry generally, for its discovery, development, and distribution of any worthwhile drugs.

We do think it is important to have the record show what they are doing, what the universities are doing, what the hospitals are doing, what the Government is doing, and what is being and has been done abroad.

In that connection, there is in the record documentation carefully prepared by members of the staff, principally by Dr. Till and Dr. Wendt, which I don't think has been controverted. As a matter of fact, Dr. Meyers, in his testimony here the other day, went into this question, and pointed out his belief about what he had found about it. He has studied these matters; he teaches pharmacology. At that time, Senator Hruska referred to a previous exhibit which shows more fully where the drugs came from.

Dr. Meyers, in his statement, says:

> Without going back too many years and penalizing our relatively young industry, let me provide some examples. Nonindustrial American investigators provided the anticoagulants, anterior pituitary hormones and possibly with help from the British, the antithyroid drugs.
>
> Most of the progress has come from European and British researchers both industrial and independent. The antihistamines, synthetic morphine substitutes, the only recently introduced local anesthetic that has any real advantage, antimalarial (in spite of our own screening program), synthetic estrogens, insecticides, and others. The most potent treatment for hypertension, the ganglion blocking agents, are British in origin. Reserpine, the most common treatment for hypertension, was brought to the attention of the British and Swiss by two Indian cardiologists. The first phenothiazine tranquilizers were synthesized in France and their significance developed by French surgeons and psychiatrists.
>
> Oral insulin substitutes were French in origin really, although best exploited by the German drug trade. Penicillin is acknowledged to be a British discovery but it is not so freely acknowledged that in the wartime developmental phase, the significant technological advance was made in a Department of Agriculture laboratory and that American industry ventured no capital.

Then he went on to talk about some of the drugs that have been developed in the United States.

> What has American industry to its credit? Following the ideas of Dubos and Waksman, it screened a tremendous number of soil samples and has contributed many antibiotics beyond streptomycin. The hydrazides that are so important in the treatment of tuberculosis are American. You have already heard opinions as to how credit for the cortiocosteroids should be apportioned. I personally would have felt that the Diuril type of diuretic, in effect an orally active replacement for the mercury diuretics that had to be injected, is a great credit to the industry. Now, Mr. Connor who appeared before you earlier says in "Drug and Cosmetic Industry" that a discovery by Dr. Schwartz of Boston, "set off a race between several pharmaceutical companies to see which one could reach the goal line first." I think that Mr. Connor misunderstands and I insist that he take some credit.

We just gave some examples. Dr. Meyers is going much further than we did.

I do not think, however, that, taking 1939 as a starting point, and comparing European discoveries and research with the United States, as you do on page 3 of "Discovery and Development," may be somewhat unfair. I don't mean that you intended it that way, because

we all know that the German, French, and British industrial plants were for a long time devoted to the manufacture of war products, and many of them were bombed and destroyed. Their scientists fled to the United States; some scientists were captured and many of them imprisoned. Dr. Berger came from Czechoslovakia, I believe, to Britain and then to the United States.

So many of them came here, and we are glad they came here. It has been since that time that we have been making better progress than we did before. But it took the foreign countries some years after the war to get back on their feet, to rebuild their factories, and resume scientific research as they had prior to the war.

I am sure you would agree with that.

Dr. SMITH. Well, Mr. Chairman, I would. I think there are several things to which I would like to direct comment. First, I do believe that all of your witnesses are entitled to their opinions and interpretations. And I would not deny that privilege. But teaching pharmacology doesn't necessarily make one an expert. I know I taught pharmacology for years, and I do not pretend to be a pharmacologist.

Now, as far as the new drugs are concerned, Paul De Haen in his review each year has presented what seems to be an authentic and generally accepted tabulation of the source of new drugs, United States and Europe, and I think Dr. Blair and I agreed, except for a minor interpretation, during my last appearance here, on that. Penicillin——

Senator KEFAUVER. We put that report in the record.

Dr. SMITH. I know. But——

Senator HRUSKA. Mr. Chairman, I think the witness should be given a chance to refer to it.

Senator KEFAUVER. Of course we want him to refer to it. But I wanted him to know that it was already in the record, so that if he were going to offer it for the record, or discuss it in great detail, he should know that we already have it before us.

(The report referred to, Exhibit No. 228, may be found on p. 10948.)

Dr. SMITH. No; I am just replying to two or three points in Dr. Meyers' paper. The statement that the industry did not put much capital or any capital, I have forgotten the exact words, into penicillin production is not true. If I recall the figures correctly, and I have them in the material here, more than $22 million of industrial capital went into that.

One comment about the discoveries in the United States of America. I think one thing that we should not ignore is that America, or the United States at least, is a new country. We are not 200 years old yet. And other countries, much older, have made, obviously many discoveries in the chemical field. But one significant thing is that in the 20 years of the so-called modern chemotherapeutic age, that is the postwar development, we have made more significant discoveries for medicine than, I think, the rest of the world put together. And I make that statement as an educator and teacher. I believe it. And I think we can document that.

Senator HRUSKA. I might say, Mr. Chairman, we have had testimony in a similar vein from Dr. Leake last week. And the chart by Paul De Haen, together with Dr. Leake's testimony, and the testimony of Dr. Smith here, certainly wouldn't warrant a statement that the

chart prepared in either exhibit 223 or 224 has not been controverted. It has been controverted, and in my opinion, quite successfully, in a number of ways, and by a number of authoritative nationally and internationally renowned witnesses.

Senator KEFAUVER. In the De Haen work, which is a part of this record, with reference to Ciba, 14 drugs were listed for Ciba, U.S.A. When we examined them, we found that all but four of them were actually discovered and developed in Ciba, Ltd., Switzerland.

(The De Haen report referred to may be found on p. 10948.)

Senator KEFAUVER. But the point is that I am glad that we are engaging in research. I am glad that we are doing much better since 1939. Taking the war years, it should be pointed out that the European laboratories and factories and their scientists were not in a position to do the work that they previously had done, as I think all of us will agree. The American industry was, of course, greatly expanded, and we are proud of that. But we want the record to show the facts on what has been done in the drug industry, and by whom.

All right. Suppose we go on for about 20 minutes more.

While we are talking about research, of which all of us are proud—we all want good research done—during our last hearings there was some discussion about just what the American pharmaceutical industry did spend for research. You have been making speeches on that subject, Dr. Smith, and presenting charts. I have noticed that even since the last hearing, the Journal of the American Pharmaceutical Association, of April 1960, to which you referred a little while ago, on page 203, shows a chart with which it says you refuted the committee chart saying that for 20 representative companies the breakdown for research was 6.4 cents of every dollar of sales in 1958. It says in this article, that your chart, which is shown at the bottom of the page, used the figure 9.5 percent for 1958.

Are you still using the 9.5 percent figure?

Dr. SMITH. I am using the figure 9 percent upward, because it is perfectly obvious that how these figures are interpreted depends on what you want to take into consideration.

Now, during the last hearings in which I participated, I believe Dr. Bambach and Dr. Browne discussed the kind of information which we had collected from PMA members, because there was some dispute over whether you were given one set of figures and we were given another set.

Senator KEFAUVER. As I recall it, Dr. Bambach didn't have any records on hand to substantiate his figure of the amount spent for research. He said that he had sent out some questionnaire, and received something back, and had either destroyed them or returned them. So he has no figures on hand whatsoever, according to his testimony, and according to Dr. Browne, to show the amount that was spent on research.

Dr. Bambach also said, "We have never purported to have an accurate sales figure." If he doesn't have an accurate sales figure, he can't have a very good percentage.

It is my understanding, also, that Dr. Bambach seems to think the sales figure includes some veterinarian, medical sales and exports.

We received the figures from the companies themselves. We also received their sales figures for drugs for 1958—not, in the case of

American Home, American Cyanamid, or Olin Mathieson, for other products they sold, but only for drugs. We have exactly what they reported that they spent for research, and we have exactly the amount of drugs they sold. For these 20 representative companies—which include the big research companies, I am sure you would agree—their percentage is 6.4 percent.

As a matter of fact, Dr. Smith, not one of them reported over 9 percent, except Ciba, and maybe one other small one. Ciba said some research they were claiming had been done in Switzerland. So it brought their figure way down.

Dr. Browne, you have the figures they report. Let's hear them.

Dr. BROWNE. Yes, sir, I have here, Mr. Chairman, the computations that are on the same basis as this chart for each company.

Senator KEFAUVER. Read them, please.

Dr. BROWNE. I would appreciate it if Dr. Smith would check these companies as we read them, and see whether they are members. I believe they are all members of your association, sir.

Abbott Laboratories, 5.6 percent.

Dr. SMITH. Member.

Dr. BROWNE. American Cyanamid, which is mostly Lederle figures, reported to us, 6.4.

American Home products, represented by Ayerst and Wyeth, 3.2.

Bristol Laboratories, specifically the laboratories, and not Bristol Myers, is 13.7.

Carter Products, represented, I believe, by Wallace, is 2.7.

Ciba, 13.9, which, as already pointed out, some of that was not spent in this country.

H. La Roche, 6.9.

Lilly, 8.8.

Mead and Johnson, 5.7.

Merck, 8 percent.

Norwich, 4.4.

Squibb Division of Olin Mathieson, 5.4.

Parke, Davis, 4.8.

Pfizer, 4.9.

Schering, 8.2.

Searle, 12.2.

Smith Kline and French, 8.9.

Sterling Drug, 3.2.

U.S. Vitamin, 5.1.

Upjohn, 8.8.

Vick, 3.7.

Warner Lambert, 5.2.

I believe counsel, in order for——

Mr. WORLEY. Vick, I don't believe, is a member, but National Drug, a subsidiary is a member.

Dr. BROWNE. So at least every company here is directly a member or represented by a subsidiary. And I could note, Mr. Chairman, 16 of the 22 are also members of the National Pharmaceutical Council, from the list that we looked at a few minutes ago.

Senator KEFAUVER. When you average this up against what they reported on sales and, of course, their sales would be what they sold abroad, which apparently is not considered by you in your figures—the figure is 6.4.

Dr. BROWNE. This actually comes to 6.3, because at the time we prepared this chart, two of the companies had not given us usable figures. When they came in, subsequently, they pulled the average down one-tenth of a percent.

Senator KEFAUVER. So 6.3 is the actual reported figure?

Dr. BROWNE. For the 22 companies, on their drug operations alone.

Dr. SMITH. Would you like me to comment?

Senator KEFAUVER. This is from their figures. They are not our figures.

Dr. Smith, in view of that, how do you continue to say we misrepresented the research figure, and that your figure of 9.5 is correct?

Dr. SMITH. Well, what I must say, I admit I say with an easy conscience now, Senator. The original figure of 9.5, as you know, we informed you in a letter subsequently submitted, was taken from figures in American Druggist, and this information was gathered, we are informed, by the editor, from reliable sources, and we have an explanation which was put in the letter as to how this was obtained.

However, there had been a difference of opinion between Dr. Bambach and Dr. Browne about the amount of sales. Incidentally, the wording in the transcript doesn't quite accurately reflect the situation. Maybe there was, unfortunately, a word left out, or it slipped away somehow, because as we informed you, our dues are determined on the basis of sales. We felt that the firms, our members, were honorable and reasonable with us, too. But we made an additional check on 19—in fact, we wrote to all the firms whose records had been subpenaed—19 of the leading firms, which supplied information to you people, and which furnished the PMA with information for 1958.

The total net sales as supplied to the Senate subcommittee was $1.94 billion for these 19 companies. It was our contention that there were included in those figures some proprietary preparations, some foreign sales, and perhaps some veterinary sales, and perhaps some medicinal chemicals. Anyway, we sent out, subsequently, a questionnaire to these firms, and asked them, and we have a copy of it, sir, which we would be pleased to give you for the record if you wish—asked them for only the figures pertainable to the actual human ethical pharmaceutical sales. And this turned out to the not $1.94 billion, but $1.59 billion.

So using your own research figures, and the way they are computed, on your figures alone we got a rounded research figure of 8 percent.

Now, that was for 1958.

Since then, as you recall, in reports that have been published to stockholders and others, for 1959, and now for 1960, a number of these firms have increased their research expenditures, I don't have the present figures here but I do remember two or three which I read in these reports. One firm, which was quoted earlier at 3.2, I think now has somewhere between 6 and 8 percent expenditures. Another firm is now over 10 percent that I recall. And there are three or four others that somehow are in my memory, but I don't recall the figures. They could easily be ferreted out.

So I think, Mr. Chairman, that perhaps the difference of opinion arises over the basic figures that are being used.

We were talking and are still talking about today's research and actual human ethical pharmaceutical sales, and none of these other things.

Senator KEFAUVER. Dr. Smith, what you are talking about here is 1958?

Dr. SMITH. That is only about the research percentage.

Senator KEFAUVER. You have 9.5 percent. Dr. Bambach says in the first place you don't include all of the companies' sales—sales of exports are not included in what was reported to him, on sales to veterinarians, and these things take research, too. They give animals similar drugs. And many other sales are not reported. Dr. Bambach also says, "We have never purported to have an accurate sales figure." If you don't have an accurate sales figure, I don't see how you are going to figure what your percentage of research is.

Dr. SMITH. We think we have sales figures as accurate as those supplied to the subcommittee. And I am sure what Dr. Bambach meant was that he didn't have the exact dollars. When one is dealing with millions of dollars, one doesn't always get the exact amount to the dollar. But I can say on examination of the information supplied to this subcommittee we found the total net sales for human ethical sales was not $1.94 billion but $1.59 billion for 19 of the companies.

Senator KEFAUVER. Of course, you can't wholly separate research for ethical drugs from research for proprietary drugs. Take antihistamines. It used to be sold by prescription. Now you can buy it over the counter. As for veterinarian products, terramycin was originally for human consumption only. Now it is being used by veterinarians in the same way. So you cannot separate research for some proprietary products from research for some ethical drugs, or veterinary research from research for human consumption, can you?

Dr. SMITH. I think you can, because I have examples here of individual expenditures for research for various products for various firms, which I thought I might use if it would interest the committee some time during the hearings, to point out the expense of doing research, and how sometimes failures can be so expensive.

Now, we are talking not about the proprietary business, but the so-called prescription business. It is true that some preparations are sold over the counter by these prescription houses, but that is because the Federal Food, Drug and Cosmetic Act proscribes that some of them be labeled for over-the-counter use. But they are not put in the proprietary category.

There is no dispute with the 1958 figures so far as I am concerned. I used 9.5 for 1958, and gave a source of reference. I still insist that the pharmaceutical manufacturing industry is spending more than 9 percent, and I think considerably more now, in research.

Senator KEFAUVER. Are you going to put your figures in the record?

Dr. SMITH. Yes; they are in, I guess.

Senator KEFAUVER. But you have no figures to put in. You have no records of what the companies reported to you in 1958. And you have no accurate record, according to Dr. Bambach, of the company sales in 1958. According to Dr. Bambach, and Dr. Browne, some veterinary, medical feed sales, and export figures were excluded. So

that we have exactly what the companies have testified to. And these are the big research companies. I am sure if you would add some of the smaller companies—they may do not do as much research—it would even figure below 6.3 percent.

I am glad they are spending a lot of money on research. But I just don't think you have figures to refute what the companies themselves have reported to us.

Dr. SMITH. Well, Mr. Senator, I disagree, because I think we do. This survey by American Druggist was based on 55 members of the PMA, as you were informed in the correspondence we sent to you. And, so far as not having the records now available for 1958 is concerned, it was explained to Dr. Browne at that time, and I believe also to the subcommittee, that it has been customary, when receiving confidential information, after the information has been compiled, to return it to the firms.

Now, I am sure that you would not cast any doubt on the ability of the PMA staff to compute this information. But, if there is going to be a dispute about figures, I think I would dispute the staff figures when you report total net sales of 1.94, and the same firms tell us that their sales were 1.59.

Senator KEFAUVER. Whether they are sold for export, or whether they are not, they are still sales of American companies. We have their detailed figures, prepared by their auditors, and furnished us here by subpena. The officials of the companies have told us that these are correct figures. We are sure that they are. We think they are the soundest figures that can be secured, because they are not from some survey, from some magazine, but they are from the records of the companies themselves.

Dr. SMITH. Well, Mr. Senator——

Senator KEFAUVER. And they show 6.3 percent.

Dr. SMITH. Excuse me. I think actually these percentages are comparatively insignificant; it is the ratio that we are interested in. I was trying to make a point, and I still would make it, that the pharmaceutical industry spends about three times as much as the average of all industry combined in research. And I think no matter how we look at the figures, no matter how we examine them, no matter how we compile them, that ratio still holds true.

Senator KEFAUVER. You have been explaining about high prices. Very frequently, witnesses from industry say that high prices are due mainly to the large amount spent on research. So, I think it is important that we have their actual figures. As far as I am concerned, I am glad they do spend a great deal on research. I think we need more research. We should encourage it. But 6.3 percent of the sales dollar is not a complete explanation of some of the higher prices that we have been hearing about, particularly when we all know that research, as defined in the Internal Revenue Code, for pharmaceutical houses, has a very wide scope, including attorney fees for the purpose of patents, and many other things that we don't think of ordinarily as research. And the companies have a 5-year period over which they can spread it, if they elect to do so. And then, of course, it comes out of their income taxes as an expense, as it should.

Some people seem to have the impression that they pay these amounts for research out of their net profits and I think that should be cleared up also.

Dr. SMITH. I think that your figure of 6.3, sir, should be roughly 8 percent.

Senator KEFAUVER. We know no way of doing it except to take their own carefully prepared dollars-and-cents figures. That is what we have. We wouldn't think that they would give us figures that were wrong. We think they are proud of their research. We have accurate figures, and your Mr. Bambach says he doesn't have any accurate sales figures.

Senator HRUSKA. Mr. Chairman, with constant repetition of Mr. Bambach's testimony, that was as of that time. The witness has already commented upon it. It certainly seems to me, however, that if Dr. Smith wants to submit the figures upon which he has computed his percentage, he should be given an opportunity to do so. And this constant reference to a particular isolated statement by a doctor who had at that time no exact sales figures for all of the 20 companies, it seems to me is probably not too relevant at this point.

Senator KEFAUVER. If you will give these figures to the staff, we will be glad to study them, and then we will put them in the record.

(The information referred to may be found on page 10992.)

I think we will stand in recess now until 2:30.

(Whereupon, at 12:20 p.m., the committee recessed, to reconvene at 2:30 p.m., the same day.)

AFTERNOON SESSION

(Present at the convening of the afternoon session: Senator Kefauver.)

Senator KEFAUVER. The committee will come to order.

I neglected to state earlier this morning that Senator Hart was very sorry that he could not be here. He wishes to attend, but he has to be at an Agricultural Committee meeting relating to wheat. He wants this conflict noted in the record. We are sorry that he cannot be here.

As I understood it this morning, we had figures from the drug companies, in answer to a subpena, giving the amount spent for research as against the amount of their total sales. Dr. Smith said he made some inquiries, and had received some other information. I thought I asked and had the agreement of Dr. Smith for him to furnish this information to the staff, so that if there is any conflict, we would have an opportunity of going into the matter and checking if there were any errors in the information submitted to us by the companies earlier. But it is my understanding now, Dr. Smith, that you will not turn the information over to the committee.

Dr. SMITH. No, I didn't say that, Mr. Chairman. I left here before the discussion was ended. So far as I am concerned, the information which we have here in tabular form will be turned over to you, and I will seek permission from the firms to have the material turned over to you.

Originally, we had informed the members that this would be held in confidence, and I think I should ask their permission. But I see no reason for not making it available.

Senator KEFAUVER. Will you make it available today?

Dr. SMITH. If I can.

Senator KEFAUVER. All right, Mr. Dixon, you may proceed.

Mr. DIXON. Thank you, Mr. Chairman.

Dr. Smith, when Dr. Chauncey Leake appeared before this subcommittee last week, he made reference to USP. In volume 19, page 3888, he had this to say:

> Since many of our Federal and State laws require the use of pharmacopoeial preparations, these standards have considerable validity. Packages labeled "USP," with reference to the particular edition involved, must conform to the standards set out, and if they are found not to do so, they may be seized and destroyed. This procedure assures physicians and patients that the drugs they get are really what is claimed for them on the labels. This is why the pharmacopoeia remains so important for us. It is our major legal guarantee that drugs so labeled are really what they are claimed to be.

Doctor, if this is true, why do we need the added complexity of trade names? Isn't the generic name enough?

Dr. SMITH. No, sir. There are several reasons. One is that the use of a trade name in America is traditional, it is part of our business.

Second, the U.S. Pharmacopoeia permits certain variations from what you might call the optimum percentage variation of ingredients, so there may be a range of 5, 10, or 20 percent.

Third, so far as the names are concerned, as I have pointed out on two previous occasions, they are intended too often to describe the chemical nature, but they don't always lend themselves to ready use.

There are many other reasons. But I just might say this. I am completely in sympathy with the U.S. Pharmacopoeia. After all, I was a member of its board of trustees for 10 years.

Mr. DIXON. Do you have any fear that unless trade names are used, the doctors might not be sure of the quality of the drugs they prescribe?

Dr. SMITH. That is so to some extent. In addition, there is a sufficient variation in the strength permitted under some of the official monographs to permit possible variation in therapeutic effect. In addition to that some of the firms, if they want to be a little sharp with their practices, could put in the minimum, rather than what I prefer to call the optimum, which would be, say, 100 percent of the active ingredient.

Mr. DIXON. As I understand it, it is just as harmful, perhaps, not to have a minimum, as it is to have more than the optimum.

Dr. SMITH. Oh, yes. The best thing is to have 100 percent if that is possible, and that is the purpose of the control laboratories of the firms that we have been discussing, the ones interested in quality.

Mr. DIXON. If you think perhaps that the physician cannot at present be sure that his patient will receive products of acceptable quality under the generic name prescribed, would you have any objection to the suggestion by Dr. Garb who made a proposal for Federal plant inspection?

At volume 20, pages 4018, 4019, and again at 4023, Dr. Garb proposed as follows:

> Fundamentally, we need a system which will assure every doctor that all his prescriptions will be filled with pure, wholesome drugs, properly manufactured, and of the correct strength. This can be done most effectively by a

system of continuous Federal inspection of all drug manufacturing and warehousing facilities in interstate commerce. By continuous inspection, I refer to the type of inspection now used for meats, in which a Federal inspector is physically present in the packaging house every minute the plant is in operation.

At 4023, he said this:

It seems completely incongruous that our great Nation is furnishing to dog and cat food safeguards which are not available for medicines for sick people. If we can afford continuous Government inspection and certification for dog and cat food, we can afford continuous Government inspection of pharmaceutical manufacturing. Such inspection would not only prevent tragedies due to impure or substandard drugs; it would also remove the reluctance of most physicians to prescribe by generic names, and could, therefore, save patients hundreds of millions of dollars.

What do you have to say to his proposal?

Dr. SMITH. Well, I would like to speak to the question of plant inspection in the Food and Drug Administration, and just dismiss the last sentence with saying that I would like to see the figures on which the individual bases the statement that patients can save hundreds of millions of dollars.

Mr. Dixon, so far as the proposal of inplant inspection is concerned, or an inspection of the plant, the Food and Drug Administration now does have plant inspection, as you know.

Mr. DIXON. Periodically.

Dr. SMITH. Periodically. However, the Food and Drug Administration, as I understand it, from the press, will appear before this subcommittee later, and will explain its role.

However, I would like, in response to the question on the attitude of the PMA toward the FDA, to read a statement on the FDA.

And, Mr. Chairman, if I could, in response to your invitation this morning, I would like to insert in the record now some of those statements that you gave me permission to insert. The others will be supplied. One has to do with concentration and competition, the other with——

Senator KEFAUVER. We will make the first one exhibit 283.

(Exhibit No. 283 may be found on p. 10831.)

Dr. SMITH. Discovery and development.

Senator KEFAUVER. 284.

(Exhibit No. 284 may be found on p. 10835.)

Dr. SMITH. The third to which I addressed myself was generic versus trade-name drugs.

Senator KEFAUVER. 285.

(Exhibit No. 285 follows:)

EXHIBIT 285

III. GENERIC VERSUS TRADE NAME DRUGS

It has been stated in this inquiry that generic drugs could be readily substituted for brand name drugs at huge savings to the drug buying public. It has been implied, too, that this could be done with no danger to the patient and no lessening in therapeutic results.

I want to state categorically that any action which would permit a substitution of any generic drug for a prescribed brand name drug is a potentially dangerous action. Doctors have always had the right

to prescribe drugs by generic and trade names, but in addition they have insisted on the patient's getting what they prescribed. This is not a matter of whim but may be a matter of tragic consequence. Let me quote briefly from a report given recently in a sister country, Canada:

In Canada it's not unusual for a manufacturer to carry out as many as 250 separate control tests on a single product, ranging from ultraviolet and visible spectrophotometry to potentiometry and crystallography. In fact, one manufacturer (Montreal) has recently shown that some 1,800 different checks were made on materials during the course of quality control study and production.

These are important because of a study conducted in Canada which showed that a manufacturer selling under generic name something that he claimed was equitable to a brand name product really showed different ingredients. The brand name product contained Sulfathiazole, Sulfadiazine, Sulfamerazine. The generic name product contained Sulfamethazine, Sulfadiazine, Sulfamerazine.

The quote from a report concerning the Canadian study, here are the results of lack of quality control based on Canadian standards.

"1. (Hospital) received chloramphenicol below strength, but the seller refused to accept the return of the product.

"2. (Hospital) has had several instances of products being excreted without disintegration.

"3. (Pharmacy) states definitely that many products are under strength.

"4. (Hospital) phenylbutazone, outer coating falls off on slight pressure (shelling).

"5 (Hospital) Sod. sulphacetamide ophth. ointment—darkens rapidly—pharmacists squeeze tubes until a clear or white ointment is found. Wastage high.

"6. (Hospital) Tablets aluminum hydroxide. Thousands discarded due to: Poor taste; lack of disintegration; therapeuticaly ineffective.

"7. (Hospital) Tablets Mephenisin 0.5 gm. Doctors claim clinically ineffective, will not use.

"8. (Hospital) Chloramphenicol Cap.; Sod. Barbital Cap. Chlorpromazine: Capsules break and leak; tablets vary in color."

DRUGS ARE NOT NECESSARILY EQUIVALENT IN AVAILABILITY

Generic drug manufacturers who trade on cheapness rather than firm reliability market only the most widely used and most profitable form of a drug. This might be a pill. On the other hand, the brand name manufacturer will provide the drugs in pills, as injectibles, in ointments, in sprays and in other forms, to fill any conceivable prescription need, regardless of which dosage form is in greatest demand.

DRUGS MAY NOT BE EQUIVALENT IN POTENCY

The official compendia permit a wider variation in content and release of active ingredient of drug formulations than brand name manufacturers wish to countenance in the face of vigorous competition. Test after test has shown that many manufacturers without interest in preserving brand name reliability take the fullest advantage of this leeway.

DRUGS MAY NOT BE EQUIVALENT IN STABILITY

The manufacturers of brand name drugs adhere to the highest standards of stability. Rigorous, expensive quality control methods assure this in brand name drug manufacture. These controls are not widely practiced by the "cheap price" drugmakers for the very reason that it is an expensive health safeguard, and they can compete on a price

basis only by cutting costs to the limit. Let me remind you of the Canadian experience to which I have referred.

DRUGS ARE NOT EQUIVALENT IN ALL LOCATIONS

Drugs promoted by the houses which feature price rather than research, controls, and service are usually marketed locally, generally reaching only a relatively small but highly populated area. No doctor or patient could rely upon being able to secure an adequate generic substitute from such firms in any pharmacy across the Nation. Many such drugs do not cross State lines, which, incidentally, removes them from FDA control.

Brand name drugs in general are available across the country. A drug that is not available when it is needed is the world's worst bargain. Healthwise this is more important than words can reveal. And any reference to the time element is not idle chatter.

(The charts referred to here, Exhibits Nos. 277 and 278, may be found on p. 10873.)

Let me demonstrate on a chart what happens when a doctor orders something in the pharmacist's stock and what happens when it has to be ordered from the manufacturer.

Furthermore, I challenge the conclusions that there are great savings to be achieved through the use of substituted generic drugs for prescribed brand name products. I believe any across-the-board, unbiased comparisons of all drugs in common use at retail outlets would reveal much smaller price differentials than exist in the bare handful of products that have been paraded before this hearing.

Let me, then, conclude this discussion with a question:

Where will tomorrow's medicine come from?

Certainly not from the drug manufacturers that rely, not on research and controls for new products, but on the discoveries of their competitors. In the past 10 years they have not discovered or produced by research a single new important drug product. This total vacuum has been maintained in a period during which ethical drug companies willing to undertake the risks of research for and marketing of new drug products have made great contributions to drug science and therapy.

Perhaps I can summarize the question of drug substitution by making these statements:

1. The discoverer and developer of a product—any product—in our way of life should have an opportunity to recover his investment and make sufficient profit to permit his stockholders some return on their investment and to permit him to explore new research areas.

2. The physician should have assurance that the product he desires for a sick person will be dispensed.

3. The public should be protected against attempts to authorize willful substitution of any product. The doctor always has had the privilege of prescribing by generic name or trade name. Traditionally in our country brand names have been a part of our life, whether they are shirts, toasters, soft drinks, cars, magazines and newspapers, or drugs. That this desire for a manufacturer to rest on his reputation for making dependable products is evident in a study made for the Pharmaceutical Manufacturers Association on actions taken against

PMA member companies and non-PMA firms. A summary has been entered in the records as Exhibit 281.

(Exhibit No. 281 may be found on p. 10966.)

Dr. SMITH. The fourth was advertising and promotion.

Senator KEFAUVER. 286.

(Exhibit No. 286 follows:)

EXHIBIT 286

IV. ADVERTISING AND PROMOTION

You have had individuals come before you to criticize the informational and promotional methods used by the pharmaceutical industry to acquaint doctors with its products. No one is questioning their sincerity or their ability, but let's not forget they have represented nobody but themselves. They were single voices speaking their own opinions. Their use of this stage may well have caused the world to believe that this handful of witnesses speaks for the medical profession. Nothing could be more misleading.

Let us put complaints you have heard about direct mail, free samples, and such promotions in proper perspective.

You can poll teachers, editors, lawyers, yes, Congressmen too; and college professors and even housewives, on this subject. Many will tell you they are flooded with booklets, letters, solicitations. They will gripe that "we receive tons of mail we never read." "It all goes into the circular file," or so they say.

Why should the members of this subcommittee have to waste their time, and taxpayers' money, airing such pointless complaints—complaints that can be heard from almost any category in the population, not just doctors?

The businessmen who pay for direct mail know all about these complaints. They have heard about them for 50 years or more. But by scientific marketing research they know that these complaints are actually unrepresentative and frequently they are made by people who have actually read the material and even bought the items offered in the scorned advertising. Many people boast they never read ads, yet they use nothing but advertised products. Businessmen continue to use direct mail despite all the announcements about "into the wastebasket," because direct mail is effective.

In my previous testimony you were given the facts of physicians' attitudes toward advertising, direct mail and detailing. These are facts based not upon the isolated opinions of a few doctors but rather upon careful national opinion sampling. These facts show conclusively that the medical profession relies upon exactly the kind of informational activities that have been criticized. If it please the members of the subcommittee I can refer again to special studies that have been made to determine how the doctors in this country who see patients in private practice gain their information on what's new in the therapeutic field.

Furthermore, doctors as a group feel that our closed circuit television broadcasts for professional people, our instructional motion pictures, our distribution of technical papers, our sponsorship of seminars and scientific meetings, all are helpful to them. Individual

doctors may disagree and they are, of course, entitled to their opinions. Does this subcommittee intend to solicit only the opinions of a few individuals, some of whom are openly hostile toward the industry, to the exclusion of qualified spokesmen for medicine?

We submit that this subcommittee has a duty to seek out the official representatives of the health team who can speak, not just as individuals, but as the leaders of their organizations. There are about 160,000 practicing physicians in this Nation organized into professional societies that truly represent their members' interests. So far as I know, none of them has yet been called to testify here.

If this subcommittee feels an obligation to get at the real facts bearing on the attitudes of the profession, it can do so faster and more accurately by seeking the testimony of representatives of medical organizations.

Dr. SMITH. The next one is prices.

Senator KEFAUVER. 287.

(Exhibit No. 287 follows:)

EXHIBIT 287

V. PRICES

None of my original testimony on the general subject of prices has been refuted, but I will briefly summarize it:

1. U.S. Department of Labor Statistics show the wholesale price of drugs increased only 3 percent between 1948 and 1958, while the wholesale price index for all industrial products has in the same period risen 22 percent, about seven times as much as drugs.

2. If prices of ethical drugs had risen as much in the postwar years as other consumer prices, the annual national drug bill would be over $1 billion more than it is today.

3. Because of my work with a trade association I cannot comment on the discussions of individual drug prices that have taken place during earlier hearings. But there is ample evidence in my previous testimony that even the costliest new drugs, which may represent research investments as high as $20 million, are reduced in price under the impact of competition and increasing production. Many specific examples are in the records of this hearing. Any attempt to prove excessive markups is doomed to failure because the profit picture in the prescription drug industry, while healthy, is competitive with other industries.

The prices of drug products sold overseas, almost all of which are made overseas, reflect wages and general living standards in those countries. The hourly wage in the United States ranges from almost four times those prevailing in Great Britain to more than seven times those in Japan. Drugs produced in those and other countries reflect those wage scales.

In real wages, however, the American drug buyer works fewer minutes to buy almost any prescription drug than anyone else in the world.

The sale of drug products to the Government and to publicly supported institutions represents an entirely different sales problem. In these instances, large savings are effected through use of marginal low-cost production, bulk packaging and delivery, through the elimina-

tion of returns, which is a costly item in ordinary drug sales, through greatly lowered costs of promotion and marketing. All these factors contribute to lower bulk sales prices. It might be pointed out here that the drugs bought by Government and institutional purchasers have been developed only through research made possible by the sale of prescription drugs at a reasonable profit.

It seems to me that there has been a kind of tacit assumption made by critics of the industry that all drug prices represent profits and that profits are the only true objective of pharmaceutical manufacturers. But the fact is that this industry has consistently shown a humanitarian concern for the welfare of people, whether or not profit opportunities have existed.

I know of no better way to demonstrate this than to show you a few of the many medicaments that have been researched, developed, manufactured and distributed at great cost, for which there is little or no prospect of financial gain. For that purpose we have reproduced a compilation made originally by the magazine New Medical Materia and headed, "There's no money in these specialties but they're manufactured just the same." It is reproduced in the record in the form in which it was reprinted in a recent issue of American Druggist.

(The chart referred to, exhibit 270, may be found on p. 10861.)

Please notice that one of these products was needed by only about five persons last year, yet was produced just the same. Others were called for in from 15 to 15,000 cases, a trivial volume by comparison with commoner drugs.

In commenting on this list, New Medical Materia said, "While there's little or no financial return from products for which there are few customers, the fact remains that the pharmaceutical industry produces many such specialties—as a service to physicians and their patients. The industry does this on the principle that, no matter how small the need for a drug when measured in number of potential users, the need is tremendous to the individual who must have the drug to avoid death or alleviate suffering."

The market for these drugs, and for many others, is so limited that they cannot be priced to return the costs. "For that reason," the magazine goes on, "manufacturers either establish a nominal price or they simply donate the products at the request of physicians." Not only are these costly items for their producers, but other expenses are sometimes incurred, like making instructional movies to help physicians use the drugs properly.

These hearings have tended to deal exclusively with economic aspects of the industry, and quite properly so. But I believe it should always be remembered that this is not an industry dedicated to the sole aim of earning a profit. It is also dedicated to advancing the welfare of humanity. This is one example of how that aim is being achieved.

Dr. SMITH. And the next one profits.

Senator KEFAUVER. That will be 288.

(Exhibit No. 288 follows:)

EXHIBIT 288

VI. PROFITS

Much has been said during these hearings about profits. In the same way that many disparagers of the industry have argued illogically that the industry is both too concentrated and too competitive, some witnesses have indicated with the same degree of illogic that the drug industry has made "enormous contributions" to American life but that its profits should be reduced.

Members of the committee and of the staff have reiterated their belief that America is well served by the quality and quantity of drugs developed and produced by the pharmaceutical industry. Only last week one witness who was quoted widely as criticizing the industry nevertheless stoutly said (on p. 3669):

> Research contributions of individual members (of the industry) have been enormous. Not only have they occurred as a result of grants in aid, but many drug manufacturing concerns have developed their own extensive laboratories.

But it is ridiculous to expect, in our system of private industry which depends upon the profit motive for progress, that the cause of medicine could be well served if the drug industry were not profitable.

In my last visit to this chamber I demonstrated that in 1958 the drug companies plowed back 44 percent—nearly half—of their profits into the business. Profits have built factories, laboratories, warehouses, and paid for elaborate and costly research that has failed. And facts have been placed into the record that prove there is no guarantee of good profits, for profit margins fluctuate in the drug industry as they do in other industries. Since 1957 the profit margin has been going down.

One of the leading investment surveys last month analyzed the performance of the industry and concluded that "contracting profits margins were the rule rather than the exception" last year. It ranks the industry "unfavorably" for expected market performance this year and for "appreciation potentiality over the 3- to 5-year pull."

The point is that any industry must be profitable if it is to continue to serve the public well. The pharmaceutical industry, now seeking cures for heart disease, cancer, and even the common cold, can hope to find them only if it can maintain reasonably profitable operation.

Dr. SMITH. And in response to your invitation, to help your subcommittee, I will give to you or to Mr. Green the additional information.

Now, on the FDA, sir, I would like to set forth this brief statement, because it explains the support that the Pharmaceutical Manufacturers Association and its predecessor organizations have given to the FDA.

Mr. DIXON. Before you read that, does it include your opinion as to whether or not the doctors would perhaps feel more free to prescribe generically if such a system of inspection guaranteeing quality was set up?

Dr. SMITH. I don't know, because I cannot look into the minds of the physicians. I would say this, however: The physicians, in my opinion, would have greater confidence in the control measures taken by some of the members of the pharmaceutical industry if the con-

trol measures for these members were increased. And it was to this, Mr. Dixon, that I was really going to speak in this short statement.

I would like to give——

Senator KEFAUVER. Do you want to file this statement?

Dr. SMITH. I would like to read it, and file it, too, sir. It is a statement on FDA. It is No. 7 before you.

Senator KEFAUVER. Let's try to hurry along now.

Dr. SMITH. I want to give you and the other members of the committee a specific suggestion for improving the present system of manufacturing and distributing medicines in this country.

In the opinion of many pharmaceutical industry leaders it is a national calamity that the Food and Drug Administration, with its present staff, budget and facilities, is unable to perform adequately its existing statutory responsibilities. The FDA laboratory facilities are scattered in many buildings in Washington and in many respects are quite inadequate for the necessary pharmacological, chemical, and other testing activities so essential to the proper performance of FDA work. In spite of the fact that FDA officials submitted final proposals some time ago for consolidating all such laboratory work in a new building to be built for their occupancy, Congress has not yet passed the necessary legislation to get construction started. In addition to the obvious effect on the quality of its work, FDA is hampered in its ability to attract competent technicians and scientists to its employ by its inadequate facilities. If you, Senator Kefauver, and the other members of your committee can assist in getting congressional approval of this important facility, you will be advancing the public interest. The support given the project by the Pharmaceutical Manufacturers Association and many industry leaders has so far been to no avail.

I might say, in addition, there have been a couple of letters written to committees, congressional committees, urging that this be done.

Even more alarming than inadequate facilities is the fact that the FDA does not have a sufficient number of competent and trained people to fulfill its present responsibilities. In hearings before the House Appropriations Committee within recent weeks, the head of the FDA, Commissioner George Larrick, testified that his field force is only large enough to permit plant inspections of the pharmaceutical manufacturers once every 5½ years—a truly alarming situation that is deplored by PMA members.

We also know that the FDA field force is quite inadequate to enable it to do the job of picking up violations for USP minimum standards of quality and strength for many drugs, particularly those produced by "coattail riding" firms that have no research programs and quite inadequate chemical, pharmaceutical, and biological control personnel and facilities of their own.

Also of public concern is the fact that for some years the new drug application sections of FDA have been inadequately staffed, especially with medical doctors who do not seem to be attracted to FDA work in sufficient numbers. PMA officials have supported FDA's attempts to obtain higher classifications for these important medical scientists, and have supported higher FDA appropriations in general, but up to date the inadequacies have not been completely corrected.

It just doesn't make sense to us, Mr. Chairman, to see Congress, year

after year, increase the budget requests for the medical research activities of the National Institutes of Health, to a current level of $455 million, approved recently by the House Appropriations Committee, and still provide the inadequate amount of $16,800,000 to FDA to support its numerous current responsibilities, including the clearance of all new drugs and the nationwide inspection of all drugs being sold in interstate commerce.

Perhaps what is needed is to have some outstanding Senator take a personal interest in the Food and Drug Administration to see to it that it gets the type of continuing support that Senator Lister Hill and Congressman John Fogarty obtain for the National Institutes of Health.

Senator KEFAUVER. I want to say here that I agree with you. I think the Food and Drug Administration does not have sufficient staff or appropriations to do many things that it ought to do, and it does need more personnel and more facilities.

Go ahead, Mr. Dixon.

Mr. DIXON. On that point, Dr. Smith, did you use the terms "therapeutic efficacy" of a product and "quality" in the same vein?

Dr. SMITH. Not necessarily. Drugs can be chemically pure and not therapeutically effective. But we hope in the field of chemotherapy that we are usually dealing with efficacious drugs and pure ones, too.

Mr. DIXON. Would PMA support a bill giving the Food and Drug Administration the obligation and duty to pass on the efficacy of drug products?

Dr. SMITH. I cannot say what the PMA would do, because this has not been considered. If you wish to ask a personal opinion, I could respond to that, sir.

Mr. DIXON. Would you?

Dr. SMITH. Yes. I believe the Food and Drug Administration is primarily a policing agency, and not a therapeutic body. I do feel, however, that the Food and Drug Administration already has sufficient, shall we say, jurisdiction to exercise considerable control over therapeutic claims, because of the way a new drug application is made. At that time, as you know I am sure, a brochure must accompany the new drug application, so that the manufacturer who is submitting the application for this new drug can explain to the FDA how he proposes to use this drug. That includes everything from chemical makeup to the dosage, the indications, the counter-indications, and so on. And on the basis of the evidence submitted at the same time to support these claims, the Food and Drug Administration determines whether or not an NDA shall become effective.

So there is the provision right now. I think what we are making a plea for at this time is that the FDA be strengthened to meet its responsibilities, particularly in the inspection of plants. And I cannot speak for the PMA in this respect, other than to read to you, as I have, the past history of PMA support of FDA.

Mr. DIXON. My point is very simple. Under the law today, the FDA has the responsibility for safety. They are looking to see whether a drug is safe or not, basically. Now, you are talking about the need for trade name products to get rid of what you call coattail riders and manufacturers who perhaps don't make drugs of as high quality.

What good would it do to give the Food and Drug Administration $10 million if there aren't some teeth in the law to do something about what you are complaining about?

Dr. SMITH. Plant inspection would aid considerably.

Mr. DIXON. On safety?

Dr. SMITH. Yes. So far as therapeutic efficacy is concerned, speaking from the industry standpoint, that is covered now through this brochure examination that accompanies the NDA. But I would add my personal comment, and that is all I can do because the PMA has not considered this question. I do not believe that the Food and Drug Administration should be a guiding therapeutic body. It should be concerned with safety, and its concern should be exercised under the provisions of the Federal Food, Drug, and Cosmetic Act.

Senator KEFAUVER. I think it ought to be pointed out here that, by statute, vaccines and antibiotics do have to be tested for efficacy, and they have to be certified, so that anyone buying them by generic name should know that they have undergone the tests required by statute. The Medical Military Supply Agency, and the Veterans' Administration, buying on competitive bids by generic names, do not only look into the safety of the product and the sanitation of the plant, but they also test the control systems to be sure that the generic-named drugs they buy from small companies—if they are the successful bidder—are good, and that they have proper efficacy.

You, of course, know that that is done.

Dr. SMITH. I don't know the details of it, sir.

Senator KEFAUVER. We will have the officials of the Military Medical Supply Agency here later on. But, anyway, it is in those fields that the Government does get a great financial advantage by bidding under the generic name. I would think that if the Government feels that they are produced under sufficient controls to give these drugs to patients in veterans' hospitals, in Walter Reed and the Bethesda Naval Hospital, where some Senators go sometimes, the physicians should also have confidence in these companies that have been inspected and their products tested, either under the vaccine and antibiotic regulations, or in those plants where the MMSA and the Veterans' Administration exercises control.

Anyway, that is just an observation that I think is pertinent at this point.

Dr. SMITH. Well, I didn't know the marketing and pricing practices that enter here. But I was under the impression that the break to which you refer comes not because a bid is under generic name, but because of the competitive bidding entered into by various firms, regardless of the size of the firm or of the firm itself. It is not the generic name itself that reduces the price of the drug, but the competitive bidding.

Senator KEFAUVER. Oh, yes. I was trying to think of the case of Schering's prednisone, Metacortone, where there wouldn't be but one bidder, I suppose. But if bids are permitted under the generic name, these little companies can participate. In the case of Ciba, if you will recall, Dr. Smith, their bid to the Government was 60 cents a thousand for reserpine which they sell to the druggist at about $39.95. That low price to the Government is by virtue of the fact that bids are under generic name.

All right, go ahead.

Mr. DIXON. Dr. Smith, in your testimony here before the subcommittee, you stated, I believe, that it was impractical for prescriptions to be written in terms of generic names, because of their length and complexity, and that recognizing this, the drug companies have, for the convenience of the physicians, derived a shorter trade name. In fact, you stated, in volume 13, page 2940, as follows:

> On the left—

you were pointing to the chart—

> are generic names chosen at random by the book published by the Council on Drugs, American Medical Association. On the right are trade names. On the left are names which I think tax the memory of most of us and on the right are names easy to remember. Now these names on the left I would like to stress are chosen on the request of physicians and others who are interested in proper nomenclature.

Yet you did not point out, did you, that the long generic names about which you complained are orginated by the drug companies themselves?

Dr. SMITH. That is not always so, Mr. Dixon, because very often the pharmaceutical firm will submit to the Council on Pharmacy and Chemistry (now the Council on Drugs of the AMA) or to some other body, a proposed nongeneric name, and the council will come up with a counterproposal. This was going on for the almost 20 years that I was at the AMA and certainly long before then. The same is true with the Pharmacopeia. Some proposals are made by industry, some are subjected to counterproposals.

Incidentally, Mr. Dixon, I doubt if I said that it was impractical, because that wouldn't be a true statement. What I said was that it was practically impossible, or something of this kind, to write all prescriptions with generic names. The majority of these substances, if they are mixtures, do not lend themselves to a complete recounting of all the ingredients. It is a time-consuming, memory-taxing procedure. And the same is true with many of the newer substances.

I would hope that I did not say, and I am sure I did not say it is entirely impractical, because that would not be a true statement.

Mr. DIXON. I was reading a quotation, Doctor, from your testimony. Perhaps you may not have meant it that way. But I assure you I was reading a quotation.

On this same point, Dr. Garb, who testified here, in volume 20, page 4039, had this to say:

> In our student project, we observed that drug company representatives often tried to claim that the drug companies deserve some special credit for inventing simple brand (coined-product) names. According to them generic (official) names are so complex and unpronounceable that the companies are doing the doctor a favor by making up simpler names. I believe a similar argument has been presented before this committee. However, there is no merit to that argument, since the drug company is usually responsible also for the complex generic name. The nomination of a generic name for a new drug is made by the company, subject to such changes as may be suggested by other agencies; such agencies consist of AMA, USP conventions, etc. I do not claim that the manufacturer deliberately tries to have a complex official name adopted. However, since he is largely responsible for the name, it seems unreasonable for him to criticize its complexity.

It appears to me, Dr. Smith, in view of the fact that the drug companies are the creators of these long, complex names, it doesn't seem

right for anyone to appear before the committee here, especially you, speaking as the head of the Pharmaceutical Manufacturers Association, and suggest that the length of these names is an argument for having short, easy-to-pronounce trade names.

Dr. SMITH. I think it is quite reasonable for me to do that, because I have been on both sides of the fence in this particular situation. As an associate of the American Medical Association, I had opportunity for years to observe this process. In spite of what Dr. Garb may have said, I am sure he feels that his statement reflected the truth. I know, and you can get this testimony from AMA people, that time after time after time, generic names were proposed to the council, and modifications were suggested. And sometimes firms simply invited the council to come up with generic names. I have been through this battle so long, that I still have scars.

Now, I would also say, as I have repeatedly, that the reason that these names often are so long isn't just to make them unwieldy, but because the scientists like to have the substance identified in some way by the generic name, so that the physician, if he is familiar with the chemical structure, can, from a label or advertised material, determine what kind of a compound he is working with. It is a perfectly reasonable thing. And yet ironically enough, so often these chemical names are so long and so unwieldy. Or sometimes a proposed generic name is usurped by someone else who has used this for some reason. And often you cannot even develop a truly descriptive chemical name.

Mr. DIXON. We understand there are three names—chemical, generic, and trade name—and the generic being its official name.

Dr. SMITH. If it is in the United States Pharmacopeia or National Formulary.

Mr. DIXON. That is right. If the names are complex, certainly the company that proposes the name must certainly bear the blame for it, must it not?

Dr. SMITH. Not the blame. He is trying to respond to the individuals who say "describe your product generically."

Mr. DIXON. If the company had suggested a very short name, do you think that the AMA would have frowned upon it?

Dr. SMITH. I have seen them do so repeatedly. The council and the nomenclature committee of the old Council on Pharmacy and Chemistry frown on these names, because they feel the names are therapeutically suggestive, or that something else is wrong with them, such as they were too similar to names already in use.

Senator KEFAUVER. You mean they frowned on some of the long names that were presented?

Dr. SMITH. Long and short, sir.

Mr. CHUMBRIS. Would you yield at this point for just one observation?

Dr. Smith, Mr. Garb also stated a little bit—a page beyond where Mr. Dixon read, and he stated as follows:

> In fact, I can say that on that point I have been convinced myself that at present I would not be happy with a generic named drug if I did not know who made it, or if I did not know that some reliable organization stands behind it.

How do you feel about that statement?

Dr. SMITH. I certainly support that. That is one of the pleas I have been trying to make for weeks.

Mr. DIXON. That was the basis of my question to you, Dr. Smith, about efficacy, and whether you would go along with the proposal for an inspector in each one of these plants, so that perhaps that doctor wouldn't be so worried about the company that made the product.

Dr. SMITH. No, no; I think there is a difference here, Mr. Dixon.

Mr. Chumbris said that Dr. Garb said that he wouldn't want to use something if he could not depend upon the firm behind it, and that is my contention. However, what you have proposed had to do with factory inspection. And while the objective of having adequate controls and other procedures in the firm is good, and we all agree with that—in fact, we have supported the FDA—how you do it, the legislative procedure, is something I would have to comment on later. I don't know what might be developed in that respect.

Mr. CHUMBRIS. On that point, Dr. Garb's answer was in answer to Senator Hruska's question, when he put it this way:

So that the argument used in favor of brand names by these detailmen is probably a valid argument, namely, that unless they know what company is making it, it would be difficult, it might be detrimental to the patient, because the product might be made by a company that does not have a good reputation and a good record for quality control.

An then came Dr. Garb's statement that he preferred a brand name rather than a generic name, if he did not know who made the product.

Mr. DIXON. Dr. Smith, in February 1944, or during the year 1944, what was your position with the AMA?

Dr. SMITH. Secretary of the Council on Pharmacy and Chemistry, and I am not sure whether I was a director of the Division of Therapy and Research at that time or the following year—I have forgotten.

Mr. DIXON. Thank you, sir. I have in my hand, Doctor, an article of yours that appeared in the Journal of the American Medical Association, dated February 12, 1944. It appeared in volume 124, No. 7. The article is entitled, "Council on Pharmacy and Chemistry. The Council on Pharmacy and Chemistry, Membership, Activities, Method of Operation, Attainments, Austin E. Smith, M.D., Chicago."

Mr. Chairman, I would suggest that this be made exhibit 289.

Senator KEFAUVER. Let it be numbered 289.

(Exhibit No. 289 may be found on page 10970.)

Mr. DIXON. I won't read all of it, Dr. Smith.

I will just read a paragraph or two from that.

If you will turn to page 434, under the subheading "Proprietary Names."

The profits to be made by a pharmaceutical house from the sale of a drug which is offered under an official name usually is quite moderate. The profits to be made from the sale of the same drug sold under a proprietary name is frequently enormous. For example, a survey in the September 1941 issue of a popular price list of drugs revealed that the total cost of an ounce of each of 19 substances under a protective name was $48.67, whereas the total cost of an ounce of each of these substances under a nonprotected name was $15.67; thus, the cost of a proprietary name to the consumer would be $33. This represents retail price, the material being reduced to terms of ounces for convenience. Included in these 19 agents were sedatives, vasoconstrictors, local anesthetics, anti-infective agents and analgesics. Some years ago a large hospital in an eastern city adopted a set of specific regulations which, in effect, did away with the expense of prescribing proprietary agents when official counterparts were

available, and unnecessarily complex mixtures and the absurd practice of prescribing names instead of therapeutically active agents. This pharmacy within 1 year effected a saving of $50,000. Thus the manufacturer frequently considers it of prime importance that his product be endowed with its own protective name.

I skip a paragraph and I continue——

Senator KEFAUVER. Let him comment.

What do you mean by that, Dr. Smith?

Dr. SMITH. Well, I was just looking at the date. What date was that?

Mr. DIXON. 1944.

Dr. SMITH. Sixteen years ago?

Mr. DIXON. That is right.

Dr. SMITH. Sixteen years ago. You will find a lot of changes in profit pictures and other things since then. You will find a lot of changes in the pharmaceutical industry. And these changes are ones that I have been discussing in February and now.

Senator KEFAUVER. What do you mean here, Dr. Smith, when you say "The profits to be made from the sale of the same drug sold under a proprietary name," proprietary meaning, I assume, trade name, "is frequently enormous." And then you recommend very directly consumers ought to buy by generic names. That is the gist of your recommendation here. What do you mean by that?

Dr. SMITH. Exactly what I said 16 years ago. At that time I believed, and I would still say, that 16 years ago there was a considerable difference between some of the proprietary remedies that were sold and those sold under generic names. But, today, when we have more competition, when we have more drugs which are available for the various diseases, we don't find this spread. I know nothing about economics of the industry in those days, except as has been traced by economists who are more knowledgeable than I am in the field. This is a statement that I made in 1944, or whenever it was, and so far as I know, was quite true then. And, incidentally, that $50,000 saving, sir, if I recall the original incident, goes back to a hospital, a large hospital in New York, which undertook this in 1931.

Senator KEFAUVER. I can't understand how you are so against generic names here today. When you were in a different capacity with the AMA, you were all for it.

Dr. SMITH. I am not against generic names. This was 16 years ago when the drug industry had different kinds of products.

Senator KEFAUVER. Drugs were still sold by either trade name or generic name, back in 1944.

Dr. SMITH. There were different kinds of products and different classes. And I showed in February, furthermore, that the spread in profits for the industry is coming down each year.

Senator KEFAUVER. Does the fact that you have changed your employment have anything to do with it?

Dr. SMITH. Mr. Chairman, I would like to make one statement. I have made this——

Senator KEFAUVER. At that time you were working for the American Medical Association, and the American Medical Association has been very interested in less expensive drugs so that the doctor can have an interest in the economic welfare of his patient. So, at that time,

you recommended generic names. And now you are working for the manufacturers, and you recommend trade names. Does that have anything to do with it?

Dr. SMITH. I think, Mr. Chairman, we might make one thing clear right now. For years, since I have been in professional practice, one type or another, my time and my knowledge have been purchasable, but I never have. When I was with the American Medical Association, I practiced certain beliefs, and I still do. And those beliefs are that we should provide the best medical care we can at the most reasonable price we can. Today the beliefs still hold, and so far as I can see, from the industry standpoint, their objectives are in line with the objectives of the American Medical Association today. I think that when you talk with the officials of the AMA in days or weeks to come, you will find support of that statement.

Senator KEFAUVER. All right.

Proceed, Mr. Dixon.

Mr. DIXON. I will skip a paragraph, and I will read the next paragraph on page 435.

One of the greatest——

Senator KEFAUVER. We will have to recess for about 15 minutes.

[Brief recess.]

Senator KEFAUVER. The committee will come to order.

Mr. Dixon, will you proceed?

Mr. DIXON. Dr. Smith, I was just about to start another paragraph on page 435 of the article we are talking about. It begins:

One of the greatest evils of the use of protected names lies in the confusion they create. The old story of methenamine being prescribed in one prescription under six different names is a standing joke in materia medica classes, and yet other examples just as questionable are evident in everyday practice. In the United States the practice among the better pharmaceutical drug manufacturers seems to be decreasing, partly because these organizations are acquiring critical medical and other technical personnel and partly because experience shows a certain amount of resentment on the part of the medical profession; there is a greater tendency to reserve proprietary and protected names for specialties of the house rather than for official agents. However, there is still room for much improvement.

It is interesting to observe the nomenclature situation in an allied country, England. There, sulfanilamide is offered under 50-odd names, including Antistrept, Astreptine, Bacterimide, Bactericide, Cepticide, Erysipitan, F1162, PABS, Septinal, Strepamide, Streptamide, Streptosal and Therapol. Can anyone hope to memorize 50 such names, none of them chemically descriptive, for one agent? Sulfapyridine is sold or prescribed under nine different names, sulfathiazole under seven. Even the Lancet, and English publication which must depend a great deal on advertising for financial security, presented an editorial in August 1943 entitled "Babel in the Drug Trade." This editorial reads, in part: "It is questionable whether the British drug trade in its present form makes the most of its great opportunities for public service. The war has revealed unexpected deficiencies * * * particularly disappointing is the attitude of parts of the trade toward the canons of ethical nomenclature * * * the Council on Pharmacy and Chemistry of the American Medical Association very rightly refuses to recognize proprietary names for articles which are included in their Pharmacopeia and National Formulary." In the marketing of original articles they say "The legitimate interests of the producer are fully served by identifying such product by appending the name or initials of the manufacturer, or by use of a general brand mark." The same must be true over here.

Dr. Smith, the first sentence of that quotation says:

> One of the greatest evils of the use of protected names lies in the confusion they create.

We have heard a great deal about confusion from doctors who have appeared before this subcommittee. Since 1944 a great number of new drugs have been brought on the market. Don't you think that the evil that you pointed out in 1944 is even greater today?

Dr. SMITH. No, not a bit. There is no conflict in that statement with the way I feel now. I have not changed my opinion one bit. I believe there is a possibility of evil stemming from the overuse of protected names.

May I go on, Mr. Dixon, or do you want a reply sentence by sentence?

Mr. DIXON. You go right ahead, sir.

Dr. SMITH. All right, sir, thank you.

Now, the second sentence and the third, I think, can be tied together with this explanation. I said that times had changed since 1944. The pharmaceutical industry has changed considerably. I have before me a list of the 25 leading prescription products in March 1960, and in that list of products there are 6 that were available back in those days. Now, we are talking about two different kinds of animal.

In those days, when we had elixirs and botanical extracts and other things, then the question of nomenclature and what I referred to in an earlier paragraph here, the difference in profit, rested on a different foundation than it does now when we are talking about chemically pure substances, or very often, mixtures, where you have to give combined drugs.

The next sentence reads:

> In the United States the practice among the better pharmaceutical drug manufacturers seems to be decreasing, partly because these organizations are acquiring critical medical and other technical personnel, and partly because experience shows a certain amount of resentment on the part of the medical profession.

I think that is true. I think what you find in practice today, that is the industry practice, is the increasing use of generic names for the older products, and trade names for those which have made some important contribution.

Now, I don't think any of us would dispute the right, at least I hope we would not—of the discoverer, that is the manufacturer who made the substance available, to use a trade name, or for anyone else who has made an important contribution, whether it has to do with the time of the release of the drug or something else that provides a real therapeutic advantage. And so I find no conflict there with either the attitude that I could express today, and my original statement that therapy and the industry have changed in 16 years.

Now, so far as this observation about England is concerned, I think it is just as ridiculous now as it was then, to have 50-odd names for one substance that was available at that time. If this were a new drug it would be different or if these firms had made original contributions it would be different. I find no conflict with that particular statement.

Now, for your reference to the Council on Pharmacy and Chemistry of the American Medical Association, refusing to recognize proprie-

tary names for articles included in the Pharmacopoeia and National Formulary; this is not quite so, nor was it even in those days, because the Council on Pharmacy and Chemistry, has long recognized a proprietary name for the firm that introduced the substance or discovered it or made an important contribution. And in more recent issues of New Nonofficial Remedies, or New Nonofficial Drugs as it is now called, you will find many proprietary names, because the council itself recognizes the need for describing the substances that are available.

Again, I can find no conflict, Mr. Dixon.

Mr. DIXON. Of course, that was written in 1944.

I have here a book called "Drug Research and Development" edited by Smith and Herrick. I understand that the Smith is you, Dr. Austin Smith.

Dr. SMITH. Yes; by chance I have that book here, too.

Mr. DIXON. I understand it was published in 1948. Correct?

Dr. SMITH. Yes, sir.

Mr. DIXON. That is 4 years later than 1944, isn't it?

Dr. SMITH. That is right.

Mr. DIXON. I understand specifically, sir, that you wrote certain of the chapters, one of which was chapter 16. On page 438 of that book, I find this sentence:

> So far as trademark or "protected" names are concerned, the council is of the opinion that medical practice is best promoted by the use of a generic name for each drug, and not by the use of a different "protected" name for each brand of the drug.

Mr. Chairman, I would suggest——

Senator KEFAUVER. Is that what you said, Doctor?

Dr. SMITH. He said the council said that. I was just reporting what the council thought.

Mr. DIXON. You were head of the council and you wrote this chapter.

Dr. SMITH. I am reporting what the council had as its opinion at that time.

Senator KEFAUVER. Is that your belief?

Dr. SMITH. No; not even at that time. If you go back into the minutes of the council you will find there were several things on which I disagreed with the council. One had to do with nomenclature. Another had to do with mixtures.

Mr. DIXON. So between 1944 and 1948, even though you were the author of this chapter, you were beginning to disagree with the council, is that correct?

Dr. SMITH. I disagreed before then in those two areas.

Mr. DIXON. Well——

Mr. SMITH. I disagreed also about the things that might be offered over the counter to the public. These are all a matter of record.

Hr. DIXON. Mr. Chairman, I would suggest that various excerpts from chapter 16 be made exhibit 290.

Senator KEFAUVER. Very well. That will be made exhibit 290.

(Exhibit No. 290 may be found on p. 10979.)

Mr. DIXON. Let me understand this correctly, Dr. Smith. You say even though you wrote various chapters in this book, and this is one of them, in 1948 you did not subscribe to the sentence I just read?

Dr. SMITH. I didn't say that, sir. I said I disagreed with the council in three broad areas.

Senator KEFAUVER. Did you disagree with the council in this area?

Dr. SMITH. In this particular instance, I disagreed, and the record will show that. It had always been my contention, and was for years afterward—and the council and I certainly got along well in spite of this disagreement—that anyone who made a worthwhile contribution to the use of a drug, or to the extension of the use, was entitled to some protected interest. I believed that that was inherently right.

Mr. DIXON. I don't find any reference here to the fact that this is the council's writings, or anything other than it is Austin Smith's writing. I will continue reading that paragraph.

Dr. SMITH. May I say, Mr. Dixon, if you will excuse me for interrupting—one thing should be clear in the record. This is a book which describes, among other things, how certain bodies function. This describes how the council functioned.

Mr. DIXON. All right, sir. I guess the record is clear, Mr. Chairman, on that point.

Do you care to make any more comment on those quotations?

Dr. SMITH. No, sir, not unless you have questions.

Senator KEFAUVER. Let's furnish Dr. Smith a copy of the excerpts, and if you want to comment on any of it, you can do so.

Mr. DIXON. He has a copy there.

Dr. SMITH. Thank you, sir.

Senator KEFAUVER. I have a copy of part of your 1944 article, which says, on page 435:

How simple it would be if the manufacturer would place the name before the council when a product is ready for the market and even before it is ready for the market and ask the council to consider its acceptability in the event the product is submitted to the council for inclusion in NNR.

At that time the council did pass on the fact that drugs were worthwhile?

Dr. SMITH. Yes, sir, on names and the efficacy of products.

Senator KEFAUVER. You said later on:

Unfortunately, altogether too many State enforcement agencies have inadequate facilities for control of these products. Under these circumstances for a considerable volume of therapeutic agents which the physician uses, the only definite assurance he has that the labeling claims for them are in accordance with sound medical opinion is the appearance on the package of the seal of the Council on Pharmacy and Chemistry.

Was that your opinion then?

Dr. SMITH. Yes, but it has changed for two reasons, sir, because the pharmaceutical industry has now more active medical departments, and more consultants, and because the Council on Pharmacy and Chemistry no longer issues a seal. It was advised by legal counsel to stop issuing a seal several years ago. I have forgotten just when that was.

Senator KEFAUVER. You did indicate there, at least at that time, that you felt there ought to be somebody to pass on the efficacy of drugs, and also the advertising of drugs, so that the physician would know what he is getting, and whether it is a useful drug or not.

Dr. SMITH. At that time I felt it was advisable, and even at this time I frequently refer correspondence to the Council on Pharmacy and Chemistry, or the Council on Drugs now, for reply, when we

receive inquiries at PMA about the efficacy of drugs. We make no attempt to reply.

Senator KEFAUVER. But outside of antibiotics and vaccines, there isn't anybody who is doing the work that was done by the council in passing on the applicability of advertising and efficacy of the drug?

Dr. SMITH. No, no, not now. There are many ways in which this responsibility is met.

Senator KEFAUVER. I know. At the beginning it was put up to the Food and Drug Administration, and they make quite a number of checks. I know the Military Medical Supply makes its investigations, as does the Veterans Administration. But this would seem to indicate that you felt then that there should be some agency to pass upon the efficacy of these drugs, and also whether the advertising properly described the drug.

Dr. SMITH. At that time, I did, sir. And if there had not occurred the changes that have occurred, I would still hold that opinion. But this morning I mentioned some of the screening devices of medical journals. I mentioned also just a few moments ago that individual firms have active medical departments now. And, in addition—general counsel can correct me if I am wrong—at that time, the Food and Drug Administration did not consider a brochure at the time of a new drug application. That was in 1944. Now, that has changed, too.

Senator KEFAUVER. Anyway, you have changed your position as to the necessity of a check, a view which you held back at that time?

Dr. SMITH. I have modified my position as to the necessity. I have not changed my opinion one bit about the need for medical supervision of claims going to physicians.

Senator KEFAUVER. My attention has just been called by Dr. Blair to what Dr. Leake said. He thinks the situation has not become better, but that it has become worse. Quoting Dr. Leake on pages 3905 and 3906:

> The American Medical Association has recently adopted general principles regarding drug advertising in the American Medical Association's scientific publications. * * * Actually, however, these principles are not as strict, nor are they as satisfactory as those which were in force before World War II.

Dr. SMITH. Well, Mr. Chairman, I have tremendous respect for Chauncey Leake. We are good friends. And I have leaned on him for advice many times. I would say this is his opinion. I would say also that when surveys are made, it would seem to indicate to me, at least, that physicians have placed considerable faith in the reliability of the firms which have good medical departments. For example, there was just read before the Royal Society of Medicine, on April 11, 1960, a paper, which included as part of its contents a chart that reads as follows:

> Has the pharmaceutical industry established a mutual beneficial relationship with physicians?

The answer was overwhelmingly yes, because it was 83 percent.

Senator KEFAUVER. Dr. Smith, we have had presented to us, a number of times during these hearings, advertising by some of the larger, more reliable, I suppose, pharmaceutical manufacturers, where it was quite apparent that there were overstatements of benefits, and either no statements or very grave understatements of side effects.

There were cases where the side effects were not even talked about at all. We have had testimony presented to us here where claims were made for one drug when the test was actually made on another one. According to Dr. Console, he thought Squibb, of which he was once medical director, was one of the better firms, but there was the practice of not giving the medical director the final authority of overstatement of benefits, understatement of side effects, improper and misleading advertising, and insufficient testing. He said he found this was true of the industry generally, so he just decided to give up and go into private practice.

The testimony that has been introduced here, in my belief, shows that the situation has not become better in recent years, and that as to these new drugs, there have been blatantly incorrect advertisements.

Dr. SMITH. Mr. Chairman, again I would say that——

Senator KEFAUVER. Even Dr. Gibson, medical director of Merck—a fine company, I am sure—agreed that one advertisement we found didn't correctly represent the situation. We have found advertisements for a number of tranquilizers where there was nothing said about addiction, in some cases even the statement that it was not addictive, when the testimony showed otherwise.

Mr. CHUMBRIS. Mr. Chairman, would you yield just a minute on this point?

Senator KEFAUVER. In a moment.

This problem, we have been told, has been cumulative. About 40 new drugs are coming out each year—I mean new types of drugs, and if each one appears in, say 5 trade names, that adds up to 200 separate trade names added to the list each year, 200 names for each doctor to remember. So that would indicate the problem is getting worse, not better—more complicated, more confusing, more names to remember, and showing a greater need for what you espoused strongly back in the 1940's.

Dr. SMITH. To begin with, the medical profession does not have to use all the drugs that come out. Its members make their choices on the basis of the information which they secure from various sources, and as they determine the needs of their patients or their practices.

Now, I cannot speak about the individual practices of any firm. I don't know them. I do know what the growing general practice is, because I saw that when I was with the AMA, and I insist I see even greater evidence of it now, even though there may be some who feel that utopia has not yet been reached in this respect. There is increasing advice from members of medical departments and from outside consultants, concerning not only the gathering of scientific data, but the way in which they are presented.

Now, when you refer to advertising, I think that we might keep in mind two types of material that is offered to the physician. There are many kinds, but for convenience I would like to divide it in two parts. There is that which goes into medical journals, and this is a reminder kind of advertising. When I was an editor of a journal, I felt it was impossible on one page to tell the whole story. Furthermore, I felt that a physician should not feel the urge to prescribe if he knew nothing about the drug, simply because he saw a single ad that mentioned a name and a dose.

I did then insist, and I still do insist that when a brochure is made available more informative information should be made available to the physician. And I think that is in line with the thinking of the Food and Drug Administration which requests a brochure at the time of a new drug application.

Senator KEFAUVER. You say you have been insisting on that to the pharmaceutical houses?

Dr. SMITH. No; I am talking about myself—not about the PMA.

Mr. CHUMBRIS. On that point, would you yield?

Senator KEFAUVER. Very well.

Mr. CHUMBRIS. Dr. Leake, on page 3897 of the transcript, stated:

As I recently explained at a scientific conference of the Pharmaceutical Manufacturers Association last February in Chicago, the essential information which every physician wants on a drug—

and then he lists 11 of them. Then Senator Carroll asked this question:

How would the doctor get that information?

Well, usually he gets it from brochure material that is sent by the drug manufacturer, and that usually is prepared very carefully. For example, the brochure prepared by Dr. Frank Berger, for meprobamate was an excellent scientific document, fully documented with all references and so on, which made a nice little book and most physicians keep that.

Then he goes on.

The point there is that the brochure is the main source of information to the doctor, rather than the medical advertisement. Is that your point, Dr. Smith?

Dr. SMITH. Yes.

Mr. CHUMBRIS. Now, what about this physicians' desk reference that is put out, which not only gives the name of the drug, and what goes into the drug, but it gives its side effects and so forth. How prevalent is this in use to the various doctors?

Dr. SMITH. I don't know. It is in thousands of desks. It is on every doctor's desk, I am told.

Mr. CHUMBRIS. Is this a good source of reference for the doctor to determine what he would like to know about a drug before he prescribes it?

Dr. SMITH. That is not complete; no. This is a reminder of disease and product. For more complete information, you would use a complete brochure, or articles that had been brought to your attention, reprints of articles, various sources. But this merely is a quick reference guide, like a dictionary.

Mr. CHUMBRIS. I notice in some of these it points out action in use, administration and dosage, contradictions, how supplied—some of them have the side effects, what should be watched out for by each of the doctors. I was just wondering.

Dr. SMITH. That is a quick reminder. It is a summary. But the individual who is confronted with the use of a new, potent drug for the first time in a serious disease usually asks for complete information to make up his mind about it. And he does not get that from a journal advertisement. He can get it from other sources.

Senator KEFAUVER. All right, let's proceed.

Mr. DIXON. Mr. Chairman, before going to the next subject, I would like to suggest that we mark as "Exhibit 291" an industry code

of ethics, "Points of Procedure for Guidance in Ethical Drug Promotion. The Medical Section of the American Drug Manufacturers Association." As I understand, that is one of the predecessor groups merged into one group, which is now the Pharmaceutical Manufacturers Association. Isn't that correct?

Mr. WORLEY. That is correct.

Senator KEFAUVER. All right. That will be exhibit 291.

(Exhibit No. 291 may be found on p. 10981.)

Mr. DIXON. And as exhibit 292, the statement of principles of ethical drug promotion passed by the PMA board of directors on May 24, 1958. That is the Pharmaceutical Manufacturers Association. This is the present code of ethics, is my understanding.

Senator KEFAUVER. All right, that will be made an exhibit.

(Exhibit No. 292 may be found on p. 10982.)

Mr. WORLEY. Do you have a copy of the first one, Mr. Dixon?

Mr. DIXON. Do I have a copy of the first one?

Mr. WORLEY. Yes.

Senator KEFAUVER. These are copies you furnished us.

Mr. DIXON. Dr. Smith, I want to call your attention to exhibit 292, which is the present statement of principles of ethical drug promotion of PMA. I want to call your attention specifically to principle No. 6, which states:

All medical claims and assertions contained in promotional communications should have medical review prior to their release.

What do you understand is meant by the word "review"?

Dr. SMITH. Reviewed by the medical department or individuals who represent that department; review with the thought of offering a favorable comment or proposals for change, it seems to me.

Mr. DIXON. Do you understand it to mean he has the absolute last word?

Dr. SMITH. That I cannot say. General counsel would have to answer that.

Senator KEFAUVER. I think you would know, rather than the general counsel, Dr. Smith. You are in close touch with these pharmaceutical manufacturers. Do they have a veto, do they have a last word, or does this just mean they review what has been prepared?

Dr. SMITH. There are two points here, Senator. One I can speak to. The other only counsel can speak to, because these were drawn up before I became associated with PHA. Your question is, Does the medical department have final review? It was only a few days ago that I just started asking some of the members of the PMA about this, and I was told in a gathering of some of these individuals that so far as their firms were concerned, that was so. I cannot tell you at this time if that is the practice for all firms. I have made no review.

Now, as to what was intended when this principle was adopted, I cannot speak to that. I do not know.

Senator KEFAUVER. All right.

Mr. DIXON. Dr. Smith, we heard testimony from Dr. Martin Seidell, formerly the medical director of Roerig Division of Pfizer, who described the use of statistical data on one drug to advertise it as if it

were the clinical test made on another drug. He was talking about Daricon and Enarax. He stated, in volume 15, page 3503:

No Pfizer laboratories or Roerig medical director had actually been delegated the authority to "approve or disapprove" promotional and advertising materials. The medical director, as a department head, reviewed for the advertising manager the materials which were designed to conform with the policies set forth by management. I could only recommend changes, as I did. However, it was up to the advertising manager and general manager to accept or reject these.

Attempts to engender arbitration had been fraught with bitterness and discord. Responsibility without authority is unjust and contradictory. I assumed responsibility for urging changes in the Enarax promotional materials, which required that these be reworked. The responsibility for rejecting my recommendations is the dual onus of the general manager who set the policy and that of the advertising manager who contrived to perpetuate the deceit.

In passing, this advertising of Enarax was the subject matter of the first case to my knowledge of false or misleading advertising to doctors that was brought by the Federal Trade Commission.

Is this the sort of review we are talking about here? Are we to understand Dr. Seidell is right? Is that your understanding of the total power of a medical director?

Dr. SMITH. I have not the vaguest idea of what goes on in that firm. I would say that in the case of other firms whom I have been able to query in the last few days, they depend heavily on medical advice and review, and even veto. There is one question I am curious about, though. It seems to me, if I recall correctly, that the general manager of Pfizer at that time was a physician. It is a point that might be checked. I don't know.

Senator KEFAUVER. I think not. I think it was a Mr. McKeen.

Dr. SMITH. No, he is the president.

Senator KEFAUVER. He was not referred to as a doctor. Anyway, do you think that is right? Pfizer is a large pharmaceutical firm. Dr. Seidell's recommendation that they stop clinical tests on one drug which they were using to advertise another drug to doctors was rejected. The advertising manager apparently wanted to sell the product quickly. Do you approve of this sort of activity?

Dr. SMITH. Mr. Chairman, I understand that this firm is to appear before the subcommittee next week. I don't think it would be fair for the committee or the firm for me to try to answer that question. I don't know what the facts of the situation are.

Senator KEFAUVER. Very well.

Mr. DIXON. Well, let's move——

Senator KEFAUVER. I am just asking you as a man who is supposed to police this field, or to have some supervision or salutary effect over the pharmaceutical manufacturing industry, whether you approve of this, assuming it is true.

Dr. SMITH. May I make a general observation, however, about these principles in PMA? During my first presentation, I said that PMA was 2 years old, and I have been with it 1 year. And in any organization, particularly where you have legal problems to be aware of, antitrust, damages, and so on, one has to move cautiously.

Mr. CHUMBRIS. Mr. Chairman, I believe that Mr. Connor—I am trying to find the page; I was looking at it earlier today, and showing it to Senator Hruska, where Mr. Connor said that his medical director—I have it now—this is on page 885.

Mr. CONNOR. I might say, sir, that in our company our medical director has the final say on advertising. To my knowledge, Dr. Gibson has never been overruled, in his medical opinion, either by management or by commercial or advertising people.

Senator KEFAUVER. That is Mr. Connor of Merck. But his medical director did say that one of their advertisements was overstated and not correct.

All right.

Mr. DIXON. Dr. Smith, I call your attention to principle No. 2, which I would think would be within your role, and one of your functions. It reads as follows:

Any statement involved in product promotional communications must be supported by adequate and acceptable scientific evidence. Claims must not be stronger than such evidence warrants. Every effort must be made to avoid ambiguity and implied endorsements. Whenever market, statistical, or background information or references to unpublished literature or observations are used in promotional literature, the source must be available to the physician upon request.

Using clinical testing on one drug to advertise another drug would appear to me to be in violation of this principle. Isn't that correct, sir?

Dr. SMITH. What do you have in mind, sir?

Mr. DIXON. I have specifically in mind the incident of Daricon and Enarax. As a matter of fact, didn't Dr. Seidell attempt to bring this matter to the attention of the predecessor of PMA? Do you know anything about that?

Dr. SMITH. No.

Senator KEFAUVER. Your answer is that you don't know anything about it?

Dr. SMITH. No, I don't know anything about it, sir.

Mr. DIXON. I will move on, then. You don't know what happened to his complaint; do you?

Dr. SMITH. No, sir; I do not.

Complaint?

Mr. DIXON. Dr. Seidell's complaint. I have a letter here referring to it.

Mr. WORLEY. I understand that is pending before the Federal Trade Commission now, Mr. Dixon.

Senator KEFAUVER. I do not care whether this is pending before the Federal Trade Commission or not. This situation is not right, and I think you would do something about it, if this statement of facts is correct.

Mr. DIXON. This should be marked as exhibit 293, Mr. Chairman.

Senator KEFAUVER. Let it be so marked.

(Exhibit No. 293 may be found on p. 10983.)

Mr. DIXON. It is a letter from Dr. Seidell to Dr. J. O'Neil Closs, executive vice president, Pharmaceutical Manufacturers Association, dated July 31, 1959. Was that before your time?

Dr. SMITH. No; I was there then.

Mr. DIXON. It reads as follows:

Dear Dr. Closs: Only a portion of my reasons for the extraordinary act of summary resignation are recounted in the enclosed copy of my letter of severance from employment as medical director of J. B. Roerig & Co. Division, Chas. Pfizer & Co., Inc.

The May 24, 1959, PMA "Statement of Principles of Ethical Drug Promotion" indicates that your president will bring to the attention of the PMA board of directors ethical code violations that come to his notice. Since I know you personally I am writing to you directly to ask you to serve as an avenue to him. At the same time I am sending a copy of this letter to other acquaintances within the board.

The Sigmamycin complaint is already a matter of record. The Enarax inquiries are probably also known to you, although the background may not be. The failure to obtain clearance from any physician on Pfizer's staff for the TAO advertisements resulted in the rejection of the proposal material by several journals although "mailers" were sent out.

That letter was sent to Dr. Closs. Dr. Seidell asked that it be called to the attention of the board of directors. I assume it was. Do you know what was done about this complaint?

Dr. SMITH. What was the date, sir?

Mr. DIXON. July 31, 1959.

Dr. SMITH. Well, Dr. Closs was still in New York then and we still had an office there. This was not presented to the board. I do not have any of the correspondence here.

Mr. WORLEY. Dr. Till has our submission on that. I think the September 1959 meeting was the meeting at which this complaint was considered.

Mr. DIXON. I believe we have nothing on that particular letter. We have some other correspondence that you submitted to us about this situation.

As I understand it, the first action of the PMA was a resolution of the board of directors to recommend to member firms that they immediately and regularly review the statement of principles, discuss it with their advertising agencies and inside advertising staff, "to the end that inadvertent digressions therefrom be avoided for the future."

Mr. WORLEY. That was in the January 1959 meeting.

Mr. DIXON. I suggest that be 294, Mr. Chairman.

Senator KEFAUVER. Let it be so marked.

(Exhibit No. 294 follows:)

[Extract from minutes of Jan. 8, 1959, meeting of the board of directors of PMA]

STATEMENT OF PRINCIPLES OF ETHICAL DRUG PROMOTION

A discussion of the article on the pharmaceutical industry, which appeared in the January 3 issue of the Saturday Review, covered many of the points in the article which have broad implications involving the industry. It was the consensus of the board that the statement of principles was still valid and should be the guiding force behind all promotional activities covering the ethical products of member firms. Other facets of the problem were discussed. It was concluded that the president would recommend to member firms that they immediately and regularly review the "Statement of Principles of Ethical Drug Promotion" and discuss the statement with their advertising agencies and inside advertising staff to the end that inadvertent digressions therefrom be avoided for the future.

Mr. DIXON. Dr. Smith, do you think all digressions are inadvertent?

Dr. SMITH. No. In no walk of life are they, I assume.

Mr. DIXON. I understand that on January 29 a letter was sent to the presidents of member companies containing this statement:

The consensus of the board was that violations, since the adoption of the statement of principles, were generally without the knowledge and approval of the company presidents involved. Instead, it was the belief that the violations were

due to a failure to control sales and promotional executives and advertising agencies who may not have regarded the statement with the seriousness that it deserves.

I suggest that that be made 295.

Senator KEFAUVER. It will so be marked.

(Exhibit No. 295 may be found on p. 10983.)

Mr. DIXON. I would assume, Dr. Smith, from what I have just read that even the board of directors feels some criticism of promotion practices is justified. Would you not agree with that?

Dr. SMITH. Oh, certainly.

Mr. DIXON. The letter suggests that the board was studying the practicability of identifying particular types of violations for the guidance of member firms. Are you still studying this?

Dr. SMITH. Mr. Worley, general counsel, should reply to that.

Mr. WORLEY. Well, it is out of the study stage. A plan of procedure has been set up, and I think Dr. Till has that in item No. 5 or 6, in the letter to her of yesterday. An ad hoc committee will be established by the chairman of the board and, if he is a complainant, by the president, each time there is a complaint in respect of a violation of the statement of principles.

This committee will be made up of noncompeting executives and technical people who are knowledgeable in the field. The findings will be made, reported to the board, and also made known to the membership after the fashion of ethics opinions in a bar group.

Senator KEFAUVER. You mean that is something you are going to do in the future?

Mr. WORLEY. That has already been established. That was established, I believe, at our January 1960 meeting. Dr. Till has all that in front of her.

Senator KEFAUVER. This recommendation refers back to January 1959.

Dr. SMITH. This procedure was adopted, Mr. Chairman——

Mr. WORLEY. February 8, 1960, meeting.

Senator KEFAUVER. I was wondering, with this complaint before you, why you waited a year to do anything.

Mr. WORLEY. We did something about that complaint, Mr. Chairman, and that appears in the record. The record of the meeting shows that Mr. John McKeen made an extensive presentation of his side of the alleged complaint. I was there throughout the meeting. He stated and showed examples of the promotional literature with Dr. Seidell's initials on them. Too, he gave in detail his reasons why he felt that the statement of principles was not violated.

Without further consideration, we being on notice that the matter was before the Federal Trade Commission, we deferred further consideration and action until the Federal Trade Commission had disposed of it. That will be taken up again after the Federal Trade Commission has disposed of that case.

Senator KEFAUVER. So you did nothing about it, then.

Mr. WORLEY. We did exactly what is stated in the extract of minutes given to the committee yesterday.

Senator KEFAUVER. When have you ever reprimanded any of these companies for this kind of practice?

Mr. WORLEY. In the 2 years there have been only two alleged violations. Both are in the hands of the Federal Trade Commission. I do not know that this is——

Senator KEFAUVER. The Federal Trade Commission has its duty, but you have your duty, sir.

Mr. WORLEY. Indeed we do. And we are quite aware of it, Mr. Chairman.

Senator KEFAUVER. What companies have you reprimanded? What action do you take to stop this kind of thing?

Mr. WORLEY. We not only have duties, we have some responsibilities, in my opinion. And that may well be the reason for the action or lack thereof, for unethical conduct. A trade association of competing firms can get itself into considerable antitrust trouble by disciplinary action, sanctions of an economic sort.

If there are violations of law, the Food and Drug Administration and the Federal Trade Commission are established to take care of this. And if my opinion is not adequate, I can supplement it by the opinion of—in my opinion, one of the leading authorities on antitrust law in the United States—Professor Oppenheim of the Ann Arbor Law School, who has examined our statement of principles and has given us a statement in writing as to his opinion. He said:

> You must not set yourself up as extragovernmental tribunals to adjudicate and penalize the offending member—

and so on.

> From then on you should depend on the member's own sense of responsibility and good faith and considering whether or not its conduct deviates from the principles, and, if so, in correcting such deviations. Unethical conduct which does not violate any law can hardly be made a convicing ground for suspension or expulsion of an association member. If, on the other hand, the conduct is regarded as an infraction of law, administered and enforced by agencies of Government, such as the Food and Drug Administration, the Federal Trade Commission, or the Department of Justice, and the courts, then you should rely on those agencies to correct the violations rather than to make yourself extragovernmental agencies of law enforcement.
>
> Any member who is found guilty by a Government agency or a court of such violations exposes itself, I suppose, to suspension or expulsion or censure from your association. That is yet to come.
>
> Since your association is a voluntary, nonprofit membership organization, you would be within your legal rights in so disciplining a member who engages in practices adjudicated by a Government tribunal as violations of law.

He has also passed upon our committee setup.

It is very easy to be critical. But you also know that we are subject to considerable penalties when we run right across the courts, the antitrust laws, and the interpretations thereof by the Attorney General and the courts.

Senator KEFAUVER. Mr. Worley, and Dr. Smith, this committee has received a great many complaints from responsible practicing physicians, some of which have been brought out here. Many, many more have not been brought up in the testimony—about unethical practices, misleading advertising, overstatement, insufficient clinical tests, exaggerated claims, insufficient warning of side effects—all of which are of great importance.

Witnesses come before us from the companies and say, "Well, industry can clean itself up, can take care of its own house, with its own code of ethics." This code of ethics has some good language

in it. But I cannot see that you have ever used the code of ethics to clean up your own house.

Mr. WORLEY. I think it is being used every day, Mr. Chairman.

Senator KEFAUVER. You depend on the Federal Trade Commission and the Food and Drug Administration. I cannot find in any of these practices anybody you have reprimanded, anybody you have suspended, anybody to whom you have threatened suspension, or anybody you have told to stop this practice.

Mr. WORLEY. We have only had two cases, Mr. Chairman, as I have stated before.

Senator KEFAUVER. Do you mean to tell me that with all the complaints about drug advertising, you know only about two?

Mr. WORLEY. The complaints have not been submitted to us for consideration.

Senator KEFAUVER. Do you have to wait until they are submitted? Don't you read the promotion yourself, and know that they are exaggerated or understated?

Dr. SMITH. The way this functions, Mr. Chairman, is shown in our statement of principles. So far as speed with which one moves is concerned, I would draw your attention to the experience that physicians have gone through over the years. Certainly, doctors have practiced in this country for a long time, and they have had professional associations. But the so-called grievance committee is a comparatively recent development. Now it is becoming effective. I feel personally, as a professional individual, and someone in a responsible position with a trade association, that we would be unwise to move precipitously without some legal backing, without some experience, and most of all without the complaints being brought to our attention.

It seems strange to me for someone to bring them to the attention of your subcommittee, and not bother writing to us, if the complaints are so serious.

Senator KEFAUVER. Of course, all you have to do, Doctor, you being a doctor, would be to read some of these advertisements yourself. You say you receive all of them. When they completely ignore the side effects of some drug that is addictive, I think all you need to do would be to read it yourself.

Mr. WORLEY. Are we speaking of advertisements or the official brochure? Advertisements do not necessarily contain a complete story. The brochure does, and it must contain all the contraindications for use, dosage requirements, and the composition. But an advertisement in a journal, be it the AMA Journal or one of the sectional journals, need not contain all of this.

Senator KEFAUVER. But the labeling material on a bottle of medicine——

Mr. WORLEY. That should contain it, Mr. Chairman.

Senator KEFAUVER. We have found in many cases that it did not. Are you endeavoring to justify this misleading advertising, Mr. Worley?

Mr. WORLEY. Quite the contrary. We are not trying to justify it.

Senator KEFAUVER. Then what is the purpose of——

Mr. WORLEY. I think our statement of principles is quite proof to the contrary. We are trying to establish——

Senator KEFAUVER. Your statement of principles sounds good, but you do not apply them. You do not do anything about them. The best statement in the world is not going to help at all unless you do something about it. I cannot find that you have done anything about your statement.

Mr. WORLEY. Are you advocating that we take unlawful steps? If we are going to change our procedures, we would like to have some legislative support, to go out and police such unethical conduct as is mentioned here.

Senator KEFAUVER. Your code of ethics here says that you are going to do certain things. All your members subscribe to it, but you are the one who has the responsibility of taking some action in connection with this code of ethics. If your code of ethics is just for window dressing——

Dr. SMITH. This is not a code of ethics. This is a statement of principles of ethical drug promotion.

Senator KEFAUVER. Whatever you want to call it. But it says, "We pledge ourselves to the following statement of principles."

Mr. CHUMBRIS. Mr. Chairman, I believe that in this, what we are discussing now, the responsibility really is on Congress, because Congress has passed an amendment to the Federal Trade Commission Act which specifically exempts false advertising, and I will quote it again.

> No advertisement of a drug shall be deemed to be false if it is disseminated only to the members of the medical profession, contains no false representation of a material fact, and includes or is accompanied in each instance by the truthful disclosures of the formula showing quantitatively each ingredient of such drug.

When Congressman Blatnik was before us, he himself admitted that the difficulty was in the law as it is now written by Congress, and his point was that whether that law as it is now on the books—whether it should be reevaluated. But to call something false advertising when the law itself sanctions it is not being in this instance—propounding the question to Dr. Smith. The question really should be propounded to Congress itself.

Now, if Congress wants to amend the law, that is something that it should consider. But the witness here is supposed to be guided, or the industry has to be guided, by the law as it is now written.

Senator KEFAUVER. I think that the labeling around the medicine is under the jurisdiction of the Food and Drug Administration.

Mr. CHUMBRIS. But that is not the type of advertising that has been directed to Dr. Smith. You have been talking about advertisements in the American Medical Association Journal, the direct mailing that is sent out to the individual doctors. Both of those are exempt from this particular statute, and I think that is one thing that has not been made clear.

Mr. DIXON. Mr. Chairman, if you read that statute, you will find that it does not sanction advertising, even to doctors, containing false statements.

Mr. CHUMBRIS. Well, that is right. And that is why there has only been this one case before the Federal Trade Commission in all these years.

Mr. DIXON. No, it does not explain that at all, sir.

Mr. CHUMBRIS. It does.

Mr. DIXON. It does not. I was in the Federal Trade Commission for 20 years. That is no explanation for the fact that they may or may not have proceeded in this field at all. We will hear from the commission. But that is no explanation for it. If it has a false statement in it, and if it goes to a doctor, it comes under that statute.

Mr. CHUMBRIS. I checked with the Federal Trade Commission, and the Federal Trade Commission up to this point has always classified the type of thing that you are talking about as not within the purview of this particular statute.

Now, the case that you just brought out a moment ago is the first case that has been brought before the Federal Trade Commission, because they believe that that went a little bit beyond the facts that you have been relating here today in your questions to Dr. Smith.

Senator KEFAUVER. We have gone somewhat afield. The issue is that the Pharmaceutical Manufacturers Association has this statement of principles, every member pledges himself to it, but you do not do anything about it, you say you do not have the legal ability to do anything about it, then why have it? If you have no legal ability to enforce it, it only becomes window dressing.

Dr. SMITH. Mr. Chairman, this is not window dressing. I think that as far as legal ability to enforce something is concerned, that is of secondary importance. The most important thing is really one's sense of responsibility. This is evident in all professions, all walks of life. Certainly, it has been true for ministers and physicians and business people.

Now, I can only say this from one practical experience. After a situation of this type was presented to the Board of Directors at one of its compartively recent meetings, I was told that members of this Board—and I do not know how many, but members of the Board, and I use the plural—went home to their offices and called in their people, and said:

"Don't you ever put me in an embarrassing position like this." Now, that has a telling effect, obviously, when it comes from top management. This is the same sort of thing that is done in all walks of life. It is done voluntarily in your profession, in the teaching profession and in medicine.

Now, according to general counsel here, we have had two instances brought to our attention, and he tells me action has been taken in each instance. In these two cases, however, there was involved a Government agency.

Now, we can only act on something when it is brought to our attention—unless you are advocating that we become a police department.

Senator KEFAUVER. I want to say this: I do not think you should abdicate your influence in carrying out this statement of principles just because a case may have been referred to the Federal Trade Commission. With all due deference to the Federal Trade Commission, a case sometimes stays there a long, long time before anything happens.

Mr. DIXON. Mr. Chairman, on that point, the Pharmaceutical Manufacturers Association is a voluntary trade association. You reserve to yourself the right to pick and choose your members, as to who you admit to membership. I would understand, having that right, you have the right to expel a member, too.

Mr. WORLEY. We do have that right.

Mr. DIXON. Why don't you expel Pfizer when it violates this code of ethics?

Mr. WORLEY. That has now been placed before the Federal Trade Commission, and the directors thought it unfair to the association, the public, and the alleged violator, to prejudge the case when an appropriate Government agency has it before it.

As I recall, Congress has decided it was an appropriate agency.

Mr. DIXON. And so you are withholding your judgment until the Federal Trade Commission action is complete?

Mr. WORLEY. Those are your words. But as Dr. Till has in front of her, you have the exact words from the minutes of the meeting.

Senator KEFAUVER. Of course, I do not know how the case will turn out. You may be withholding your judgment for many, many years.

Mr. WORLEY. I see no reason to expect that.

Senator KEFAUVER. In the *Carter's Little Liver Pills* case, the company was in court 17 years until the decision came down that there is no liver in connection with the pills. But the legal decision of a claim, of a case before the Federal Trade Commission, and what is ethically right for membership, is entirely a different thing. I think you agree.

How you can let clinical tests on one thing be used to advertise another drug? How you can sit by and let a company use the names of fictitious doctors, and admit it, and still put off any action? That does not indicate that you are going to do anything about your principle of ethics.

Dr. SMITH. We did not admit those things, Mr. Chairman. To the best of my knowledge, they were not specifically brought to——

Mr. DIXON. The Pfizer Co. has publicly agreed that there were no such doctors. I cannot quote from memory, but I remember reading that somewhere. To my belief, I think I am correct, they have conceded that this was perhaps an indiscretion on their part. But I do not think there is any disagreement with the fact that there were no such doctors, as was pointed out in a magazine article dealing with the product Enarax.

Dr. SMITH. There is a difference between an indiscretion and an actual violation of ethics. I think that general counsel would remind me of that if I attempted to go beyond it.

Mr. DIXON. Mr. Chairman, to make the record complete, Mr. John Lear wrote an article in the Saturday Review, September 5, 1959, entitled: "The Case of the Substituted Drug."

Senator KEFAUVER. If it is not already an exhibit, let it be made one.

Mr. DIXON. Exhibit 296. If it is already an exhibit, we will refer to it.

(Exhibit No. 296, referred to earlier as Exhibit No. 240, may be found in part 18, p. 10531.)

Mr. DIXON. After this article appeared, we were furnished a letter that you wrote, Dr. Smith, to Mr. John E. McKeen, president of Charles Pfizer & Co., dated September 18, 1959. I would suggest that be made 297.

(Exhibit No. 297 may be found on p. 10984.)

Mr. DIXON. I would like to read this. It is very short.

Dear John: Several individuals have asked me about the challenge offered in Lear's latest article in the Saturday Review of Literature when he refers to referral of the subject which he discussed to the board of directors of the PMA. I have informed these inquirers that the subject will be on the agenda for the forthcoming meeting of the board. In view of this, is there any information that you would care to have me circulate to the board members prior to the meeting? If so, I would like to suggest that I receive this within the next day or so in order that it may be received by the board members before they leave for the meeting. Otherwise it would have to be presented to the members when they arrive in Washington.

We were not furnished anything that was sent in answer to your letter, Dr. Smith, so I do not know whether reply was sent to you or not. But I would suggest that this extract from the PMA minutes referring to this subject be made 298.

Senator KEFAUVER. Let it be made exhibit 298.

(Exhibit No. 298 may be found on p. 10984.)

Mr. DIXON. I will read this extract from the minutes, PMA board of directors meeting, September 30, 1959.

Senator KEFAUVER. Was that following the letter you just read?

Mr. WORLEY. It was in response to the letter, Mr. Chairman.

Mr. DIXON. This says:

John E. McKeen, on behalf of Chas. Pfizer & Co., Inc., submitted a detailed documented reply to the charges made in an article entitled "The Case of the Substituted Drug," in the September 5, 1959, issue of Saturday Review that Pfizer had violated articles 2 and 6 of the PMA statement of principles of ethical drug promotion in respect of the promotional material distributed on its product "Enarax." Mr. McKeen specifically denied that his company had violated any of the principles.

In view of the fact that "The Federal Trade Commission is presently conducting an investigation into representations inserted in advertising media on behalf of the product Enarax which is marketed by the J. B. Roerig Co. Division" (letter of June 4, 1959, from FTC to Pfizer), and Pfizer has submitted a response and is continuing to respond to the FTC in this regard, it is the consensus of this board that consideration of the charge of violations of the statement of principles is inappropriate, at least until the findings of the FTC are available.

Senator KEFAUVER. So it was postponed until the Federal Trade Commission action.

Mr. DIXON. Yes.

Dr. Smith, we have heard much recently from witnesses about good and bad companies. For example——

Senator KEFAUVER. Let me ask you about membership in PMA. How about smaller companies? Mr. Seymour Blackman stated that his company had been recommended by other manufacturers. He said he sent an initial application fee on three separate occasions, and then, according to the record at page 1047, he said:

We were never notified as to any transgression, shall we say, nor were we allowed to do penance for our sins. We did not know we had stepped out of line. We were never given a chance to correct anything we were doing.

Is membership open to smaller companies?

Mr. WORLEY. That was answered, Mr. Chairman, at our February 23, 1960, appearance. There is a lot of other testimony going with it, which at that time you read.

Mr. Blackman, for his company—and I do not know the name of it—as I recall, stated he applied to the American Pharmaceutical

Manufacturers Association 2 or 3 years ago. That is one of the associations that is a predecessor of PMA. He has not applied to the PMA. So how can the PMA state what action has or could be taken on an application? He has not filed one.

Senator KEFAUVER. But PMA succeeded ADMA, did it not?

Mr. WORLEY. And APMA. He filed with the APMA. I think the record showed, as you gave it to us in February——

Senator KEFAUVER. You mean his application is no longer current with the PMA?

Mr. WORLEY. There was no continuing entity. The APMA went out of existence. The ADMA went out of existence. The PMA is a new organization.

Senator KEFAUVER. But you took over their functions and members.

Mr. WORLEY. We did not take them over, as such. We invited them all to join, and they all joined. There was provision that there would be automatic acceptance of all members of APMA and ADMA. I thought that was explained for the record in the February meeting.

Senator KEFAUVER. Did you look over the companies that had applied and that had been turned down or not acted upon?

Mr. WORLEY. We reviewed none of the work that had been done by the two previous associations.

Senator KEFAUVER. So, in effect, by not looking over the applications that had been filed for membership, it was, in effect, an exclusion, was it not?

Mr. WORLEY. I do not agree with you at all. I do not know what action was taken by APMA. I only know what you say Mr. Blackman said.

Senator KEFAUVER. Shouldn't you have notified them that they were supposed to file another application?

Mr. WORLEY. No. Why should we? This is an organization that stands available. He can file if he wishes. A lot of people decide they do not care to join the PMA. We do not solicit membership, Mr. Chairman.

Senator KEFAUVER. Do you have a procedure where any one of the other companies can keep a new applicant out, a blackball procedure or majority vote?

Mr. WORLEY. I have never heard of it, and I have been with them since the organization.

Senator KEFAUVER. Are they voted into membership by majority?

Mr. WORLEY. It is in the bylaws. I thought we went into that in the February meeting.

Senator KEFAUVER. Tell us briefly.

Mr. WORLEY. They have to be passed upon by the committee on membership, which is appointed by the board of directors. They are then submitted by that committee to the board of directors. If passed by a majority vote, they proceed to the members, and the members approve it. There are three distinct steps. It is very simple, and no gimmicks.

Senator KEFAUVER. So the membership committee and the board of directors are the ones that have to pass on it?

Mr. WORLEY. Three. The committee on membership, the board of directors, and the membership.

I might add we admitted a new member at our last meeting.

Senator KEFAUVER. Does each company have a single vote or do the larger companies have more?

Mr. WORLEY. Under the bylaws, no company, large or small, has more than one vote. And I might add that no company is entitled to have more than one director on the board of directors.

Senator KEFAUVER. On page 403 of your 1959–60 yearbook, there is Merck & Co., Inc., Chemical Division of Merck, Sharp & Dohme. Do they get three votes?

Mr. WORLEY. That is what we call multiple listing. Some of these larger companies like to have representatives of their corporate divisions on our sections, which are working groups in the association, but each company has only one vote. That is a matter of permitting them to have membership on the sections.

Senator KEFAUVER. They have one vote for each of these divisions?

Mr. WORLEY. They can have representatives at a research and development section meeting or a medical section meeting, for example, because they are so large, and they have several units. They prefer to have the several units listed as members. But the company has only one vote. That is spelled out, I think your staff will confirm, in the articles of incorporation and bylaws that have been filed previously with the committee.

Senator KEFAUVER. All right.

Mr. DIXON. There is a distinct advantage, is there not, Dr. Smith, in being a member of PMA?

Dr. SMITH. I would hope that the members enjoy privileges of exchanging information in the section work. I do not know what distinct advantage that may have for a member. Only the individual members can tell you.

Mr. DIXON. In appearing before official bodies on any given matter, or in giving advice to the Congress, or to the Food and Drug Administration, it would be an advantage to be a member of the PMA, or you would not be representing them.

Dr. SMITH. It would have the same advantage as my being a member of the AMA, but I couldn't speak for the AMA or the PMA unless authority is given.

Mr. DIXON. Mr. Chairman, to make the record complete, the last document sent to the committee was the extract from the minutes of the February 8, 1960 meeting of the board of directors, and it is a report of the committee which reviewed the principles of ethical drug promotion. I think it should be made 299.

Senator KEFAUVER. Very well. That will be made part of the record.

(Exhibit No. 299 may be found on p. 10985.)

Mr. DIXON. I had started to say, Dr. Smith, that we have heard recently from witnesses about good and bad companies. For example, Dr. Chauncey Leake stated in volume 19, page 3952, as follows:

I might add that it is my own personal opinion that the responsible drug houses and the major ones I am thoroughly familiar with, I am confident that the sense of responsibility is there. But they have this ambivalent picture that you have pointed out. Not only are they responsible for the beneficial use of their drugs and the fact that they should be free from harm, and so on, and the information get across, but they also are in business, and that is the type of the business. It is to make money.

He talks about responsible drug houses in this statement. Would you agree with him that there are some not as responsible as others?

Dr. SMITH. You are now speaking of PMA members or the drug industry in the United States?

Mr. DIXON. I am talking about PMA members and any others.

Dr. SMITH. I would assume that all the members of PMA have a mature sense of responsibility.

Mr. DIXON. Dr. Console had this to say on the same point. Senator Kefauver asked him:

So you have no individual criticism of E. R. Squibb & Son. Your disillusionment was with the industry rather than with any one company?

Dr. Console, at page 3808, replied:

No. Actually, I feel that Squibb is one of those houses, the older well-established conservative houses, that does try to resist the abuses. But very frequently they are trapped into going along with some practice because not to go along with it would mean essentially being pushed out.

Dr. Bean made the same point on page 3672, when he stated:

What is the organizational structure in which physicians and a manufacturer of drugs, untrained in medical problems, may find themselves at odds? I am not concerned with the many fine pharmaceutical companies which exercise scrupulous caution in releasing new drugs * * *. Many fine pharmaceutical manufacturers got their start from the foresight and enterprise of a pharmacist or a physician who founded the company. There was a sense of obligation to the public as well as pride in the good name of the company. The public was not solicited to buy. But two changes have occurred. Some large chemical manufacturers have entered the drug field or bought out established businesses. The professional founders of other companies have become remote with the passage of time and industrial expansion.

Aren't these statements from responsible physicians of serious import to the PMA?

Dr. SMITH. PMA has not considered that individual statement. Maybe I can reply this way and be more helpful; I am not being evasive: The Pharmaceutical Manufacturers Association has had a liaison committee with the AMA since PMA inception, and before that, for 2 years, there was liaison with the ADMA and the APMA, to discuss matters of mutual interest, how the industry might serve the medical profession better, and how the medical profession might bring to the industry the thoughts that its members have concerning improvements for the medical profession and its patients.

Similarly, a liaison committee has been established with the American Association of Medical Colleges, and a number of meetings have been held between PMA officers and the AAMC.

Now, it seems to me, Mr. Dixon, that a number of these things, about which there might be a difference of opinion in the years gone by, are things that the industry seriously today is considering to see what can be done about doing the best possible job. It is turning to the deans, to the American Medical Association, to pharmacy. Where else can it turn for advice and guidance?

Mr. DIXON. Dr. Smith, when Dr. Garb was before the subcommittee, he stated that in a 3-year study he found the ads and policies of a number of pharmaceutical companies were thoroughly reliable and honest. However, he stated that it was found that the majority of the mail ads were unreliable to the extent that a physician trusting them could be seriously misled.

What is your reaction to this statement?

Dr. SMITH. I do not know whether that is so or not. I have not examined all the ads. There was a time when the Council on Pharmacy and Chemistry used to examine all the ads of the firms that had products accepted by the council, with a view to determining whether or not these ads were as acceptable as those submitted for the Journal of the AMA, or if they conformed with the statements of actions and uses in NNR.

Subsequently, legal advice was to the effect that the council should quit trying to supervise what was going on in collateral activities. Since then, I have had no reason to examine all advertising.

Mr. DIXON. You were with the council at that time, were you not?

Dr. SMITH. Yes, sir.

Mr. DIXON. That change took place by 1955?

Dr. SMITH. No. This was the famous rule 11, which was omitted back in the forties. The council seal was dropped some time during the middle fifties.

Mr. DIXON. And you state that that was dropped on advice of counsel?

Dr. SMITH. Yes, sir.

Senator KEFAUVER. You mean the seal was dropped, or your cessation of examining and testing drugs, and looking at the reliability and truthfulness of literature was dropped?

Dr. SMITH. Both of those, sir. The looking at all the literature, in an attempt to control these collateral activities, if you want to call it that—was dropped on the advice of counsel. Also, the seal or acceptance program was dropped on the advice of counsel.

Senator KEFAUVER. What counsel was that, Doctor?

Dr. SMITH. In the forties, it was a firm by the name of Burke and a few others, and in the fifties it was Kirkland, Flemming, Green, Martin & Ellis.

Senator KEFAUVER. Would you furnish the committee, or would Mr. Worley, with copies of the legal opinions?

Dr. SMITH. The AMA can. I do not think I can get their records.

Senator KEFAUVER. You were the head of the council at that time.

Dr. SMITH. I can ask for them. But they are their personal records. I certainly will ask for them, sir.

Mr. WORLEY. We will ask for them, Mr. Chairman.

(The information referred to may be found on p. 10993.)

Senator KEFAUVER. If you can get them, or we will write the AMA and ask them also.

Mr. DIXON. Along that same line, Dr. Garb, on page 4060, had this to state with reference to what he considered the attempt to imprint the brand name on the doctor's mind, while making it difficult for him to discover the generic name:

> A second abuse is the attempt to imprint the brand name, private product name, on the doctor's mind, while making it difficult for him to discover the generic name. Usually this involves large letters for the brand name, and small letters for the generic name.

Then he gave us an ad for Declomycin, which he said is about average for the industry. I would like to have that shown around.

He said that ad is about average for the industry, and that the generic name is not easy to find. Would you agree with that?

Dr. SMITH. No; it is right under the trade name.

Mr. DIXON. You think it is just as large as the name of the product?

Dr. SMITH. This is what the council dealt with all the time. One of our rules for generic name required it to be close to the trade name.

Mr. DIXON. I am going to show you one on Dimetane, also submitted by Dr. Garb. I will ask you to find the generic name on that one.

Dr. SMITH. I find it most difficult to comment on the individual firms, since some of these may be before you again.

Mr. DIXON. This is just your observation.

Dr. SMITH. Where is the rest of this?

Mr. DIXON. That is it. Can you find the generic name on that one?

Dr. SMITH. No; I cannot.

Mr. DIXON. I will tell you where it is, and I will send you a spyglass or magnifying glass. If you look close to the "D" there, you will find it.

(The exhibit referred to may be found in part 18, p. 10494.)

Dr. SMITH. Yes.

Mr. DIXON. It is pretty hard to see.

Now, I will show you another one with respect to Nilevar. I will ask you if you can find the generic name on that one?

Dr. SMITH. It is not easily found. Oh, yes, it is, in the first paragraph.

Mr. DIXON. It is in the first paragraph?

Dr. SMITH. Yes. The name of the substance, and then it says "brand of," and then the generic name is given. This, too, I might say, is in line with the editorial policies of the Journal of the American Medical Association. At least, when I was there we always insisted if the trade name was used, the generic name also had to appear the first time the trade name was used, which usually was in the first paragraph.

Mr. DIXON. So that one is acceptable.

Dr. SMITH. I would say this is identifiable.

Mr. DIXON. How about the one before it?

Dr. SMITH. I could not subscribe to that, certainly not.

Mr. DIXON. Then it would mean that some companies are less responsible than others, as we have been told by these responsible doctors who have testified here?

Dr. SMITH. So far we have had three firms involved. I would assume that it is quite true that some firms have different opinions about some of these things. I think that probably is much more so, however, for other firms that have not been discussed.

Mr. DIXON. Dr. Garb in testifying also pointed this out, on pages 4071 and 4072:

A third abuse is the "blitz" or "saturation" campaign. * * * In this type, the doctor is swamped with advertising mail for a single product. Here are eight ads (for Decadron) received by me in a short time. Six of the eight refer to experience with a single patient. In a comparative study of drugs, a physician will often study 50 to 100 patients, or more, before summarizing the data, and reporting it. Here a single patient is made the subject of an ad.

Then he pointed out:

A fourth abuse is the use of clever and expensive advertising gimmicks. The physician doesn't need tricks; he needs honest, reliable information about the new drugs. Here are same examples of wasteful advertising gimmicks—

and he produced them, and passed them up to the table.

Dr. Smith, what is your reaction to what Dr. Garb characterized as "blitz" or "saturation" campaigns, or to these gimmicks?

Dr. SMITH. So far as gimmicks are concerned, he is quite right. Gimmicks are not necessary to impress on the thinking of an individual physician the importance of a drug. But I believe that this is common practice in the United States in the selling world.

Now, so far as the blitz is concerned, I suspect that that is a matter of opinion. As I pointed out this morning, I made inquiry to a number of firms, because I was curious about the figures that appeared in the newspaper. I found great contradictions existing with many of these figures. I quoted some of them. I can give more if you wish. And I find also that when one examines the amount of material that arrives in the mail, it varies with the individual, and the kind of practice that he has.

I don't know what constitutes a blitz. But I do know this. Every time a mailing goes out, it doesn't go to every physician. They are very selective. And as I mentioned this morning, that was specifically so for Smith Kline & French, who had been accused of sending out 150,000 big packages, and actually it sent out 6,000 to new doctors who were going into practice.

I think, Mr. Dixon, that sometimes it is often a matter of opinion, but it may depend a great deal on the emotional response of the individual. I can say this: So far, not one of these things has been brought to the attention of the PMA through this liaison committee with the American Medical Association.

Senator KEFAUVER. In your statement of principles, do you deal with the matter of advertising? I mean, the amount of advertising, or the inclusion of the generic name.

Dr. SMITH. No, sir.

Senator KEFAUVER. You have recommended, at least in times past, that the generic name ought to accompany, and be given substantially as much prominence as, the trade name.

Dr. SMITH. No. I did say, and I would still say, that it ought to accompany it; it ought to be given sufficient prominence for the average reader to understand and see it. The degree of prominence depends upon the kind of copy that you are working with. You can set it with certain point type, or you can do it by some other technique.

Senator KEFAUVER. Do you do anything to try to get the members of the PMA to be sure that the generic names are included, and that they are carried in a place where they can be found?

Dr. SMITH. Time after time such things are brought to the attention of the members of the PMA, and its working staff, which is the most important thing, through guest speakers before the PMA sections and at the annual meetings of the PMA. And, incidentally, Dr. Chauncy Leake appeared before the midwestern meeting of the PMA in Chicago, in February. The advice of such men as him has been actively sought. That is why there is a liaison committee with AMA and AAMC.

Senator KEFAUVER. All right. Anything else, Mr. Dixon?

Mr. DIXON. Would you agree, Dr. Smith, with Dr. Garb's further statement to the subcommittee that the most helpful advertised drugs are not new drugs?

Dr. SMITH. I wouldn't, no sir. I really would not.

Mr. DIXON. That was his observation to the committee. Would it be a fair conclusion to say this, that among all your members, it is the purpose of their advertising to persuade a doctor to prescribe by trade name?

Dr. SMITH. If they have a vested interest in a trade name, I would say yes. But there are many member firms who also make available generic name products—I mean, PMA members.

Senator KEFAUVER. You mean, if they have a patent or a license, something that can be sold by a trade name, you try to stress the trade name?

Dr. SMITH. Yes. But sometimes they use a trade name when they don't have a patent, because they have made a pharmaceutical refinement which is of considerable benefit to the sick person.

Mr. DIXON. There is no patent on hydrocortisone, and several companies make a hydrocortisone produce under their own trade name, and they advertise it under the trade name, and they try to persuade the doctor to prescribe their particular trade name drug; isn't that true?

Dr. SMITH. Probably so, like the shirt manufacturers.

Mr. DIXON. Dr. Leake stated to us, on page 3906 of the record:

> These brochures usually follow the promotional pattern of emphasizing the trade name of the new drug, urging its use in certain diseased conditions, telling in what form it is available and what dose to use. Often included are blatant testimonials. Essential pharmacological data is seldom offered. Then the ads in professional periodicals often plug the trade name, merely as a reminder to read the brochure.

Would you care to comment on that, sir?

Dr. SMITH. I am not sure I understand the point, Mr. Dixon, because I think that this is quite a common practice. The original brochure that goes out is a source of general information to the physician. He is urged by reminder advertising to use the product, and very often he is urged to send in for a brochure. Unless I misunderstood this, there is nothing unusual about this.

Mr. DIXON. One of the points that jumps at me from this quotation is this one:

> Often included are blatant testimonials. Essential pharmacological data is seldom offered. Then the ads in professional periodicals often plug the trade name, merely as a reminder to read the brochures.

Dr. SMITH. I don't think that is so. In the brochures that couldn't possibly be so. In many of the extensive booklets you have seen, which are of an informational nature, it certainly is not so. In an advertisement, as I said earlier, there is no attempt to tell the whole story in one page or half a page or a quarter page or an eighth page. That is a reminder kind of advertising.

Mr. DIXON. Mr. Chairman, in 1944 also Dr. Smith wrote another article which appeared in the Journal of the American Medical Association. I think as a matter of information it should be made exhibit 300.

Senator KEFAUVER. Very well.

(Exhibit No. 300 may be found on p. 10986.)

Mr. DIXON. In it, Dr. Smith makes observations on laboratory and clinical appraisal of new drugs. I think you pretty well subscribed at that time, did you not, Dr. Smith, to the view that a doctor should be given a great deal of information?

Dr. SMITH. I did then, and I still do, Mr. Dixon. I remember this paper very well.

Mr. DIXON. Then you agree with the statement of Dr. Leake to the effect that consideration should be given to essential information which is appropriate for any physician to know in connection with a drug?

Dr. SMITH. I do, yes.

Senator KEFAUVER. I notice in this paper you also say—

Frequently the pharmaceutical manufacturers concerned with the development of a new product has neither the facilities nor the personnel to investigate the drug adequately. This is particularly true of clinical investigations.

Dr. SMITH. Where is that, sir?

Senator KEFAUVER. That is on page 960.

Dr. SMITH. The beginning of the second paragraph, left column?

Senator KEFAUVER. Yes.

Mr. DIXON. "Frequently" is the first word.

Dr. SMITH. That I think still stands, sir. That was back in 1944. I mean, the effectiveness of that statement was true then. But as I have said repeatedly, it has changed. Firm after firm that you could call could tell you about the change in scientific personnel in their firms. In fact, a recent PMA survey reveals how many scientists there are in the industry now.

Senator KEFAUVER. There were good firms back in 1944 and not such good firms—just like there are at the present time, except that there are many more drugs now.

Dr. SMITH. There is a difference in practice, Mr. Chairman. The practice in the early forties was different than it is now.

Mr. DIXON. As I recall some of the discussion we had with the doctors last week, it left me with the understanding that the manufacturers dispensed a great deal of information to physicians on animal studies, but that a great deal of time went by before the doctors received any information on human consumption of drugs. In fact, Dr. Leake said this, at page 3947:

Most physicians would be wise to wait for impartial evaluation of new drugs before using them. This evaluation is made in the medical profession by the council on drugs of the American Medical Association * * *. Physicians in general should be skeptical of the descriptions of new drugs offered by pharmaceutical manufacturers in flamboyant brochures or advertisements, or by overenthusiastic detail men. It is safer and cheaper for physicians to restrict themselves to such drugs as are described in the United States Pharmacopoeia, the National Formulary, and New and Nonofficial Drugs. It would seem that physicians would be much more efficient and economical in the use of drugs if they would put adequate time in the study of fundamental principles in pharmacology, and if they would carefully follow the reports of the council on drugs of the American Medical Association * * * If they would restrict the drugs they use to those admitted to New and Nonofficial Drugs and the United States Pharmacopeia, we might find that a great deal of our excitement over the costs and use of drugs would quiet down. We might even find that we could begin to use drugs effectively for the promotion of optimum health. This is what people really are interested in.

Do you agree with that?

Dr. SMITH. Well, you have several points here. I should take them up one at a time or there is bound to be confusion. And when I make these statements, I think that probably it should be clear that so far as most of the members of the PMA are concerned, and I suspect all of them, they are not worried about what the council accepts and doesn't accept, because these members for long years have had contact with the council, and have had their products reviewed.

So let us talk about the animal and human studies. I certainly subscribe to Dr. Leake's feeling that there ought to be human as well as animal studies. After all, any of us who have had anything to do with experimental work, know you cannot necessarily depend on a transferral of animal studies to humans. That is why, for example, four of us were interested in preparing that paper in 1944.

Now the second thing, about overenthusiasm, that physicians should be aware of that—I believe that is so, and I think that responsible members of the industry would say that physicians should be aware of overenthusiasm. I cannot argue with that, no matter who may resort to overenthusiasm.

So far as confining oneself to USP drugs, it would be possible to practice medicine if one were to confine oneself only to the drugs in the United States Pharmacopoeia. But one could not practice the best medicine, in my opinion, because there are so many other useful drugs that are not in the USP. Furthermore, as you know admission to the Pharmacopoeia takes time. I believe you have talked to Dr. Miller about this.

Now so far as studies of pharmacology are concerned, I agree that physicians would be wise to study the reports of pharmacologists. I think it would be a good thing. In fact, all of us, and I am sure this is true for most of the members of industry, have been urging that physicians look into the full details of drugs, and certainly they have been urging that pharmacologists' reports be studied. After all, don't they turn to pharmacologists for their work?

Now confining oneself to the use of the council on drugs reports, again, the council moves more slowly than is justified. No, I don't mean quite that. I mean the council moves more slowly, because of the nature of its deliberations than would best serve the interests of these physicians who want to get what is new as quickly as possible to their patients. I know the way in which they have moved. I have worked with them. They are deliberate, and wisely so. But I think that you will find, when you talk with officials from the AMA, that it has been suggested that the council reports be speeded up, and made available more quickly.

I think, Mr. Dixon, that in the final analysis, the use of drugs should depend upon the physician, and I believe that he has the right to get adequate information. But when it comes to choice of drugs for the sick person, he, better than any impartial body, knows what is best suited to that patient. And if he does not know, he shouldn't prescribe it.

Senator KEFAUVER. Do you have any other questions?

Mr. DIXON. That is all I have.

Senator KEFAUVER. I have just one or two questions.

I see in the Washington Post of April 19 that you drugmakers plan a study of cost impact. I think we might put this in the record, so I won't have to read it all. That is exhibit 301.

(Exhibit No. 301 may be found on p. 10991.)

The article says in part:

The Nation's organized drugmakers plan a full-scale study of the impact of drug costs on the American public, it was announced here last night.

The factfinding is designed to consolidate information never before assembled by any source, public or private, said Dr. Austin Smith—

and so forth.

Findings will be made available for public examination.

Is that going to be carried out?

Dr. SMITH. Yes, sir. That was one part of the nine-point program that I mentioned in February. This has already been discussed with representatives of pharmacy, and other individuals, and also with representatives of medicine. In fact, I discussed it by telephone just 2 days ago, with the president of the AMA.

Senator KEFAUVER. Then you are disturbed about the price situation?

Dr. SMITH. No, I didn't say I was disturbed. I said I want the facts. So does the PMA.

Senator KEFAUVER. But you wouldn't be studying it, unless there had been some contention about the matter, I don't suppose?

Dr. SMITH. Oh, there has been contention. I think that is a very conservative statement, sir.

Senator KEFAUVER. We hope our committee can help you get some facts that might be beneficial to your study.

Dr. SMITH. We are serious about this, Mr. Senator. We want the facts.

Senator KEFAUVER. We have been trying to get the facts out here. I am glad to see you are going to make this study. I am sorry it is going to take 2 years.

Dr. SMITH. I didn't see 2 years. Is that in the newspaper?

Senator KEFAUVER. No. I correct that. The article refers to a 2-year-old association.

When do you expect to have this ready?

Dr. SMITH. I don't know, sir, because I would like it to be complete. The board of directors at its recent meeting said this was to be done, and it is now a question of working out the details with individuals who can contribute knowledge or can find others who will do this. I would like to speak in terms of months, but I don't mean only 3 or 4 months. This is much too serious for that.

Senator KEFAUVER. Is this going to be done by you, or are you going to have it done by outside people?

Dr. SMITH. We have not decided whether this will be done by staff hired by PMA, or whether it will be put in the hands of a special committee and staffed by PMA and others. I suspect the latter.

Senator KEFAUVER. I read a little while ago, from the first of your articles back in 1944, that frequently the drug manufacturers do not have the facilities to investigate drugs, and so forth. I find in your other article, in December 1944, in your summary:

Recent history contains too many instances of disastrous results that have followed incomplete or inadequate investigation on new drugs.

That was your statement back then?

Dr. SMITH. Yes. That is one of the reasons the Food and Drug Administration came into existence.

Senator KEFAUVER. Yet when you were head of the council, you abandoned laboratory testing?

Dr. SMITH. Did the council do any laboratory testing?

Senator KEFAUVER. I am asking whether, when you were head of the council on drugs of the American Medical Association, you abandoned laboratory testing?

Dr. SMITH. No. This was after I left the council. The chemical laboratory did chemical tests. The clinical data and animal data were gathered on the outside from various sources. I was no longer secretary of the council when the chemical laboratory was discontinued.

Senator KEFAUVER. Anyway, chemical testing has been abandoned by the AMA?

Dr. SMITH. That is right.

Senator KEFAUVER. Then the seal of approval was abandoned because of some legal opinion?

Dr. SMITH. But this chemical laboratory procedure, Mr. Chairman, in part is being done by the American Pharmaceutical Association now, and there are several groups including the PMA, and I understand the AMA, that have hopes of again having an independent type of chemical laboratory test evaluation.

Senator KEFAUVER. Back when you were head of the council, or at least part of the time when you were head of the council, the AMA would not take advertisements of new drugs in their magazine unless the drugs had been tested or approved by the council on new drugs?

Dr. SMITH. That is correct.

Senator KEFAUVER. That practice has been abandoned now?

Dr. SMITH. It was not tested by the council but accepted for inclusion in NNR after review. That meant reviewing the evidence that was available. That has been abandoned. What they have now is an advertising committee that reviews the evidence submitted sometimes by the council, sometimes by others. This determines the admission of advertising.

Senator KEFAUVER. Do you know Dr. Hans Popper?

Dr. SMITH. Yes.

Senator KEFAUVER. Do you think he is a knowledgeable man about liver problems?

Dr. SMITH. I have great respect for Dr. Popper.

Senator KEFAUVER. You stated, back in 1944, that there had been disastrous results, because of incomplete and inadequate examination. In testimony before our committee, Dr. Popper pointed to the development of a number of new drugs—Thorazine, Nilevar, Marsilid, and Diabinese—which are causing problems; some of them are causing jaundice and liver damage. So don't you think that if there were testing of these new drugs, as used to be done by the council, many of these problems might be avoided?

Dr. SMITH. No, sir. The more potent the drug—this is almost inevitable and pharmacologically and clinically you will find this is so—the greater the possibility of a toxic reaction. Furthermore, some individuals are hypersensitive to those drugs, so there is no way of

predicting what individual may respond unfavorably to a drug or in what dosage. And this is part of the risk of, you might say, modern medicine. But the physician weighs the advantage and the disadvantage. Our objective is to make sure that the drugs are as least harmful as possible.

Senator KEFAUVER. In any event, in the case of Marsilid, for instance, we had quite a number of advertisements saying nothing about side effects or about jaundice. One ad later did mention it casually. But if there were some check, as the council used to do, on the advertising on these new drugs, there wouldn't have occurred these fatalities from Marsilid.

Dr. SMITH. I don't know anything about this drug. But I think possibly what happened was that these things developed after the drug had been in use for some time. This is very commonly the case.

Senator KEFAUVER. That is exactly what we have been complaining about, and what you were complaining about back in 1944, that drugs shouldn't be put out and sold until they had been in use for some time, so that the side effects could be ascertained.

Dr. SMITH. Sometimes there may be 5,000, 10,000, 15,000, 20,000 doses administered, or even people treated, before this series of events occurs. That is one of the unpredictable things about drugs.

Senator KEFAUVER. Dr. Popper said these drugs were causing liver damage, and that there should have been something included to warn the physician about it.

Dr. SMITH. I would assume any firm that would get that information, if it were supportable, as soon as it receives it, would make the warnings available. So one would have to consider the advertising before receipt of such knowledge and the advertising afterward.

Senator KEFAUVER. Dr. Popper says that the physician should certainly have the most accurate advertisement possible in connection with it.

Dr. SMITH. I am sorry. I didn't hear you.

Senator KEFAUVER. I say Dr. Popper said that—Mr. Chumbris has just called my attention to the fact that Dr. Popper said later in his statement that in some drugs the risk is greater than in others, and only the physician can decide as to whether the risk should be taken in any individual case.

Dr. SMITH. I agree. That is what I said, sir.

Senator KEFAUVER. But testing such as used to be done by the council, and the dissemination of full information about side effects, would certainly be helpful to the physician in making up his mind.

Dr. SMITH. The dissemination of full information should be undertaken, sir. So far as the council on pharmacy and chemicals is concerned, perhaps there is confusion about its testing. It had a chemical laboratory at AMA headquarters to help it. But its review of animal and human data depended on evidence gathered for it elsewhere, sometimes by pharmaceutical firms, sometimes supplemented from independent sources.

Senator KEFAUVER. Anyway, they gave their expert knowledge as to whether this was sufficient, whether it was adequate?

Dr. SMITH. And from time to time——

Senator KEFAUVER. I didn't understand that the legal side of it had anything to do with the requirement that the council didn't continue testing. I thought it was only the seal.

Dr. SMITH. The legal counsel advised giving up the seal, because of the threat of antitrust actions. So far as the chemical laboratory being discontinued was concerned, that was a separate decision of the board of trustees of the AMA.

Senator KEFAUVER. That has nothing to do with any legal side.

Mr. WORLEY. I don't believe so, Mr. Chairman.

Senator KEFAUVER. That is my understanding.

Mr. WORLEY. That is my understanding, too.

Senator KEFAUVER. We will see about that from the opinions of the AMA lawyers, when they testify here.

Mr. Chumbris, any questions?

Mr. CHUMBRIS. Well, I was just going to point out one thing further, on Dr. Popper's statement. Even the Department of Health, Education, and Welfare, a letter was put in the record. He pointed out that the doctors were fully warned about the effects of these particular drugs, and that they should take every possible precaution. And that is in the last paragraph of that letter from the Deputy Director, or Deputy Commissioner of Food and Drug—that the doctors were warned, fully warned. But because, as you pointed out, Dr. Smith, because of the potency of this particular drug, and the great value to certain types of diseases, it was up to the doctor in the last analysis to make the decision whether the drug should not be used. So there was plenty of precaution in this particular instance. There is no question about it.

Dr. SMITH. And as is inferred there, and as Dr. Popper, I am sure, had in mind, sometimes it is a long time before you see some of these unanticipated reactions. It is not lack of testing. As human beings we don't respond like clockwork, as one might hope, when it comes to the use of drugs.

Mr. CHUMBRIS. I have no further questions.

Senator KEFAUVER. Mr. Kittrie?

Mr. KITTRIE. Dr. Smith, I would like to ask a number of questions, primarily to clarify some of these matters. Also because of the fact that you have played such a prominent role in the medical field, and in the drug field, I would like to have some of your comments and responses.

I would like, for one thing, to get your response to the proposal for Federal inspection and certification of all drugs, as was proposed here. As you know, it was proposed that all drugs should be certified and inspected in the same way that is done with meat, or with dog food. And I really wanted to get your response, (*a*), whether you are in favor of it, and also what would be involved if we undertake that particular practice?

Dr. SMITH. Speaking as an individual now—because so far as I know, the PMA has not given any consideration to this—I believe it would be an unnecessary costly exercise for the Government and the taxpayer to have inspection of every drug and certification. I feel also that there probably isn't realization that if you were to attempt to provide inplant inspection for all the steps that might occur, you might end up with the sort of situation that exists in the biologic field, where you have many individuals inspecting many steps.

I think, then, sir, that one has to consider just briefly the general principle, and then wait for any legislation, if any should be suggested at some time, because one's comments would depend on the nature of the legislation.

Senator KEFAUVER. Would Mr. Kittrie yield at that point? There is a statute that requires substantial inspection in the case of antibiotics and certain preventive vaccines. It seems to be working satisfactorily. There seems to be no delay in getting the vaccines on the market and getting them certified.

Mr. Kittrie, would that point be relevant to the inclusion of other ethical drugs under the statute, regarding vaccines and antibiotics?

Dr. SMITH. My reply to Mr. Kittrie would suggest that in my opinion it is not necessary.

The antibiotics, when they were originally proposed, were—shall I use the word "unstable"—I am sure that is the wrong one, but an unstable type of compound. And they didn't necessarily respond to tests, and other things, in the same way that chemically pure substances do. And yet one thing we cannot overlook is that the manufacturer, as you know, pays for the certifications. And if this were to be extended for all manufacturers to all drugs, it wouldn't reduce the cost of medication.

Mr. KITTRIE. Now I have some other questions. Since the question was raised concerning PMA's practices concerning the admission of drug companies, and since this may be a misunderstood thing, I just wanted to check. Your organization does not determine the prices of drugs for members that belong, do you?

Dr. SMITH. No.

Mr. KITTRIE. The fact that you admit or do not admit somebody does not really constitute an economic discrimination against the drug company that is not admitted?

Dr. SMITH. No. Mr. Kittrie, the essential points of PMA membership can be expressed this way. Principal emphasis is on exchange of technical information on production and general distribution. I don't mean price policies or anything like that. I mean quality control, research and development, location, personnel, facilities, and such things as that.

Mr. KITTRIE. Well, since the general jurisdiction of this committee is with antitrust matters, I just wanted to be sure that we have it clear that not admitting somebody to PMA does not constitute an antitrust type violation, does it?

Dr. SMITH. No.

Mr. KITTRIE. Now as you know, and you have followed these hearings, I am certain, there have been all kinds of complaints made, and all kinds of suggestions made, as to how to deal with some of these problems, if they exist. Now some suggestions are for Government action, some are for action by various public organizations. Some of these suggestions are for action by the American Medical Association. And some suggestions are for action by the industry.

Now as far as any endeavor on the part of industry to regulate itself, did I understand it right that you feel that maybe the industry cannot regulate itself properly, because if you endeavored to do that, you may be subject to antitrust charges? You are less able to regu-

late yourselves than the medical association, or the legal association are, by expelling members, or by disbarring members?

Dr. SMITH. Subject to correction by counsel—and I find I am particularly prone to be corrected by counsel—I believe that the Pharmaceutical Manufacturers Association can exercise increasing guidance for its members. The extent to which it can move, however, would depend on some very careful study of the laws of this country, and of the role of trade associations in the U.S. way of life, and our economic way of life.

I have no doubt about what can be done eventually, if there are needs for change. I do have considerable reservation, however, about the speed with which things can move. And I can only be guided by lawyers about the way things can be done.

Mr. KITTRIE. Now yours is a very central organization in this field, and I wonder if for purpose of conclusion you could just in a few sentences give us some idea as to what you may consider being problems in this field, and what you can do about it?

Dr. SMITH. There are so many things, Mr. Kittrie; do you mean in the promotional field, in the health field? May I make these comments, and withdraw the question?

I believe that the responsibility of any association like any profession is to provide the special service that it is supposed to be able to provide, and at the same time assume a citizenshsip role and provide leadership in this respect. This is why I suppose I am an ardent free-enterprise man, and I am an ardent association man.

Now, I do believe that the Pharmaceutical Manufacturers Association has the responsibility of encouraging its members to make available the best possible drugs under the best possible conditions for doctors to use for sick people. I think in addition, the Pharmaceutical Manufacturers Association has a role to play in good citizenship in this this country. And I say this with deep conviction—that the PMA has already indicated an interest on both scores by its 9-point program, and by some of the other steps it has taken. But I would urge your indulgence in remembering that it is only 2 years old.

Mr. KITTRIE. Now, actually, as you become stronger, and you have some more time and so on, would you be willing to look into such questions as cross-licensing and all the other problems that have come up? Do you feel that some of these things are within your domain to look at, or do you feel that these are things that should be—you do not want to do this, and somebody else should look into it?

Dr. SMITH. There are a number of problems we can engage in, but there are some we cannot. My feeling is, again subject to correction by counsel, that we cannot get into such things as patents or cross licensing. We cannot get into pricing practices. We cannot get into the establishing of marketing practices. Those are a few examples of things I believe we cannot get into. But I am subject to correction by counsel.

Mr. KITTRIE. Thank you very much, sir.

Dr. SMITH. Thank you.

Senator KEFAUVER. Any other questions of Dr. Smith? If not, we thank you very much, Dr. Smith. You will let us hear from you about these other figures you have talked about?

Dr. SMITH. Yes, sir. Thank you, Mr. Chairman.

Senator KEFAUVER. We want to try to keep our record as clear and accurate as possible. We have received a letter from Merck & Co., pointing to an error in one of our subcommittee charts. I will ask Dr. Blair to explain it and put a memorandum in the record.

Dr. BLAIR. Yes, Mr. Chairman. Very briefly, the error arose from the failure to include certain stock that was issued between 1949 and 1952. It was purely a mistake on our part. We should have caught the issuance of this stock, and we did not. We are very grateful to Merck & Co. for calling it to our attention.

I suggest that this memorandum reflecting the correction which we have made, and the redrafted chart, which also reflects the corrected figures, be put into the record at the point where the presentation was first made.

Senator KEFAUVER. All right. That will be done.

(The material referred to, exhibit 44a, may be found in part 15, p. 8089.)

Senator KEFAUVER. We stand in recess until Tuesday morning at 10 o'clock. The witness list will be available tomorrow.

(Whereupon, at 5:30 p.m., the committee recessed, to reconvene at 10 a.m., Tuesday, April 26, 1960. The proceedings of that hearing may be found in part 20.)

APPENDIX

EXHIBIT 223

Examples of drugs developed by United States drug companies in specific product areas not studied by subcommittee

Substance (United States)	*Date*	*Substance (United States)*	*Date*
Epinephrine	1897	Chlorthiazide	1957
Ephedrine	1924	Nalline	1952
Estrone	1930	Benadryl	1945
Mercurochrome	1919	Pyrabenzamine	1946
Divinyl ether	1930	Aminophylline	1937
Neosynephrine	1942	Theophylline	1950
Cholorpheniramine	1948	Varidase	1951
Prantal	1952	Hyaluronidase	1951
Fibrin foam	1941	Amyl nitrate	1860's
Undecylinic acid	1949	Hexyl resorcinol	1924
ACTH	1950	Isoniazid	1952
Pectin	1941	Probenecid	1950
Inversine	1956	EDTA	1953
Nitrofurazone	1946	Furdantin	1953
Diamex	1953	Glutamic acid (mental alertness)	1943

Examples of drugs developed by United States drug companies in specific product areas studied by subcommittee

Cortisone and its derivatives (synthesis)	Novobiocin
Meprobamate	Erythromycin
Ultron	Diabinase, a modified sulfanilamide-urea
Derivatives of phenothiazine	Vitamin B_1
Derivatives of sulfonilamide	Vitamin B_6
Derivatives of testosterone	Vitamin B_{12} (3 months prior to British)
Penicillins V, O	Folic acid
Penicillins G, benzathine	Biotin A
Broad spectrum antibiotics	Pantothenic

EXHIBIT 224

Examples of drugs developed by U.S. university and other noncommercial laboratories:

Substance	*Location*
Antibiotics:	
Nystatin	State of New York.
Streptomycin	Rutgers University.
Synnematin	State of Michigan.
Candicidin	Rutgers University.
Neomycin	Do.
Streptothricin	Do.
Tyrothricin	Rockefeller Institute.
Tyrocidine	
Gramiciden	

EXHIBIT 224—Continued

Substance	*Location*
Antibiotics—Continued	
Totomycin	Jacques Loeb Foundation.
Chloromycetin	Yale University—by Dr. Paul Burkholder.
Fillipin	University of Illinois.
Fumagillin	New York Botanical Garden.
Polymyxins A and D	(U.S. Department of Agriculture) England.
Bacitracin	U.S. Army.
Salk vaccine	University of Pittsburgh.
Other drugs:	
Dicumarol	University of Wisconsin.
Heparin	Johns Hopkins University.
Fibrinogen	Harvard University.
Fibrinolysin	Do.
Vitamins	Vitamins will be considered in later hearings. They have not been included in these lists since, in the majority of cases, the number of workers involved makes it difficult to assess credit to any single individual or country.

EXHIBIT 225

Examples of foreign-origin drugs in specific product areas studied by subcommittee

Substance	Country of origin	Date
Antibiotics:		
Penicillin	England	1929
Spiramycin	France	1953
Griseofulvin	England	1954
Kanamycin	Japan	1958
Aerosporin (polymyxin B)	England	1947
Diabetic drugs:		
Insulin	Canada	1922
Tolbutamide (orinase)	Germany	1954
Hormones:		
Aldosterone	Switzerland and England	1939
Androsterone	Switzerland	1931
Dehydroisoandrosterone	do	1934
Testosterone	do	1935
Pregnanediol (isolation)	England	1927
Progesterone	Switzerland	1934
Desoxycorticosterone	do	1939
Ovarian extract	do	1913
Estrogenic substances	Canada	1943
Dienestrol	England	1938
Sulfas:		
Sulfanilamide	Germany	1935
Sulfamethazine	England	1941
Sulfisomidine (elkosin)	Switzerland	1944
Tranquilizers and central nervous system drugs:		
Meperidine (demerol)	Germany	1939
Methadone (analgesis)	do	1942
Mephenesin	Great Britain	1946
Xylocaine	Sweden	1946
Promethazine (phenergan)	France	1947
Reserpine	Switzerland	1952
Hydroxyzine (atarax)	Belgium	1952
Chlorpromazine (thorazine)	France	1953
Promazine (sparine)	do	1954
Mepazine (pacatal)	Germany	1954
Benactyzine (suavitil)	Denmark	1954
Ritalin	Switzerland	1958
Perchlorperazine (compazine)	France	1954

EXHIBIT 226

Examples of foreign-origin drugs in specific product areas not studied by subcommittee

Foreign drugs, substance (foreign origin)	Country of origin	Date
Acetanilid	Germany	1886
Acetophenetidin (phenacetin)	do	1890
Aminopyrine (introduced in medicine)	do	1896
Antabuse (disulfram)	Denmark	1948
Antianthrax serum	Italy	1895
Antihistamines	France	1937
Antipneumococcal serum	Germany	1910
Antipyrene (introduced in medicine) phenazone	do	1884
Arsphenamine (salversan)	do	1850
Atabrine (Quinacrine)	do	1930
Aspirin	do	1898
Barium	do	1775
Benactyzine (tranquilizer)	Denmark	1954
Benzoic acid compounds	Germany	1832
Chlorine	Sweden	1774
Chloroform	France	1831
Chlorquanidine (antimalarial)	England	1954
Cinchona (brought to Europe)	Spain	1642
Cocaine (for anesthetic use)	France	1868
Cod liver oil (for rickets)	England	1782
Codeine (isolation)	France	1892
Cyclopropane	Canada	1929
Colchicine (gout)	England	1934
Cowpox vaccination	do	1774
Demerol (meperidine)	Germany	1939
Dextran (plasma extender)	Sweden	1944
Dextrose (synthesized)	Germany	1887
Digalen (digitalis preparation)	Switzerland	1904
Digitalis (introduced in medicine)	England	1780
Amorphous digitalen (isolated)	France	1845
Digitoxin (isolated)	England	1930
Dilandid (introduced in medicine)	Germany	1926
Diphenyl Thiourea	Switzerland	1958
Diphtheria antitoxin	Germany	1912
Ergot (used in medicine)	England	1560
Ergotoxine	do	1906
Ergotamine	Germany	1920
Ergonovine	do	1937
Ergo kryptine	do	1937
Ergocristine	do	1937
Dihydroergotamine	do	1943
Dihydroergocristine	do	1943
Dihydrocornine	do	1943
Dihydrokryptine	do	1943
Ether	do	1540
Ferrous iodide	Denmark	1700
Ferrous carbonate pills	France	1832
Hydralazine (apresoline)	Germany	1950
Ichythyal (used in dermatology)	do	1886
Insulin protamine	Denmark	1936
Insulin	Canada	1922
Iodine	France	1812
Mandelic acid (urinary infections)	England	1935
Ipecac (introduced in Europe)	Holland	1648
Meclizine (Bonamine—motion sickness)	Belgium	1951
Magnesium trisilicate	England	1936
Myleran	do	1953
Novasural (mercurial diuretics)	Germany	1920
Methadone	do	1942
Quinine isolated	France	1920
PAS (para-aminosalicylic acid)	Germany	
Pentolinium tartrate	England	1953
Phenmetrazine	Germany	1953
Petn	Sweden	1943
Phenylbutazone	Switzerland	1946
Pilocarpine	England	1947
Phenindrone	France	1909
Pituitrin (oxytocic)	do	1909
Plasmoquine	Germany	1926
Polyvinyl pyrrolidone	do	1943
Privine	do	1941
Potassium iodide (epilepsy)	England	1857
Potassium bromide	do	1935
Rochelle salt	France	1862
Triodothyromine (cytomel)	England	1952
Thiocyol	Switzerland	1898
Urethan (lukemia)	England	1946

EXHIBIT 227

"NEW CHEMICAL ENTITIES"[1] INTRODUCED BY SEVEN U.S. DRUG COMPANIES, 1949–58

1. CARTER PRODUCTS, INC.

One product, Miltown (meprobamate) listed for the 10 years, is a slight molecular modification of mephanesin of British origin.

2. AMERICAN HOME PRODUCTS

Seventeen products listed. Three are of French origin:

Phenergan (antihistamine and tranquilizer) is sold under license from the French firm, Rhone-Poulenc.

Sparine (tranquilizer) is similar to phenergan; the product was already in the public domain and American Home secured a patent on dosage form only.

Therusistan (antihistamine) also derives from French work.

Six others are European in origin:

Antabuse (treatment for alcoholism): Danish origin.

Wyamine (central nervous stimulant): German origin.

Ansolysen (hypotensive): English origin.

Mysoline (one of many brands of primidone): British origin.

Bicillin (mixture of two penicillins—procaine and benzathine—both of which are modifications of the original British discovery).

Thiosulfil (molecular modification of sulfa): German origin.

Another was the result of simultaneous work in Switzerland and in a U.S. university. This is Estradurin (estradiol) which is a female sex hormone.

The remainder are not significant; they are as follows:

Cyclamycin: Company's brand of oleandomycin (antibiotic) sold under license from Pfizer.

Aurel: One of the many anticholinergics on market.

Ambutonium bromide: Another of the many anticholinergics on market.

Suvren: Tranquilizer .

Cothera: Cough medicine.

Enzactin: Brand of glyceryl acetate used in fungus infections.

Baseljel: One of the many antacid agents.

3. SMITH KLINE & FRENCH

Eighteen products listed. The most important—Thorazine and Compazine—are of French origin. Compazine is listed three times in various forms, i.e., Companzine, Compazine dimaleate, and Compazine ethandisulfonate. In addition, two others—Stelazine and Temaril—are also structural modifications of the French discovery (phenothiazine). Thus 6 out of the 17 are of French origin. Cytomel (a thyroid preparation) was developed by Glaxo in England and licensed to SKF.

Of the 11 remaining drugs, 4 are not listed in the 1959–60 Blue Book and either so unimportant as not to be listed or have actually been abandoned as useless. These 11 are:

Neo-Penil: Form of administering old penicillin G (not listed in Blue Book).

Tetronyl: Vaginal anti-infective (not listed in Blue Book).

Resodec: Ion exchange resin tried out as diuretic (not listed in Blue Book).

Feojectin: Injectable iron solution (not listed in Blue Book).

Sul-Spansion: Very slight change on old sulfa (sulfamethazine) in sustained release form.

Benzedrex inhaler: Old benzedrine inhaler changed slightly because of addiction qualities of benzedrine.

Prantal: One of many anticholinergics and similar to other.

Darbid: Another of many anticholinergics and similar to others.

Toryn: Cough sirup.

Quotane: Topical anesthetic similar to many others.

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[1] According to Paul de Haen, New Product Survey Single Chemical Entities, 1949–58.

Sources: Patent agreements subpenaed by subcommittee; testimony on drugs before the subcommittee; Goodman and Gilman, "The Pharmacological Basis of Therapeutics" (Macmillan, 1955, 2d ed.); Schmidt, J. E., "Medical Discoveries" (Charles C. Thomas, 1959); Kremers and Urban, "History of Pharmacy" (Lippincott, 1951, 2d ed.); miscellaneous monographs and articles.

4. CIBA PHARMACEUTICAL PRODUCTS, INC.

Fourteen products listed. Mr. Haines, president of Ciba, stated at the subcommittee hearing that of new products listed in the De Haen report for his company, 10 were of Swiss development and 4 from the U.S. subsidiary.

The 10 foreign developments are as follows:

Serpasil: Brand of reserpine developed by Ciba, Switzerland.
Elkosin: Molecular change on sulfa. Swiss origin (not listed in 1959–60 Blue Book).
Tessalon: Cough medicine. Swiss development.
Bradosol bromide: Cough lozenge. Patent expired.
Apresoline: Hypotensive. German origin.
Perandren Phenylacetate: One of many brands of injectable testosterone (male sex hormone). German origin.
Ritalin: Antidepressant. Swiss origin.
Antrenyl bromide: Another anticholinergic. Swiss origin.

The four from the U.S. company are:

Singoserp: Modification of side chain on reserpine which itself is Swiss development.
Ecolid: Hypotensive.
Itrumil: Thyroid product.
Carethose: Gastric antacid developed by Michael Reese Hospital, Chicago.

5. SCHERING CORP.

Most important in list of 10 drugs for Schering are Meticorten and Meticortelone (cortical steroids—prednisone and prednisolone). Both of these products are involved in interference proceedings with the origin of the discovery still unsettled.

Two are European in origin:

Polaramine maleate (antihistamine): Similar to Trilafon.
Methostan: Methylandrostenediol, a sex hormone. Swiss development.

A third, Trilafon (tranquilizer) is a phenothiazine modification derived from the French work. (Schering has a U.S. patent.)

Another, Teridax, is not a drug but a diagnostic color agent.

The most important of the remainder is Chlortrimeton maleate: Widest selling antihistamine.

Remainder appear to be of little significance. They are:

Dormison: Sedative.
Prantal: Another anticholinergic like many others.
Neraval sodium: Modified barbiturate called thiobarbiturate.

6. THE UPJOHN CO.

Fourteen drugs listed. Three relate to cortical steroids. Two of these, Cortef Fluid and Solu-Cortef, are injectable forms of hydrocortisone first introduced by Merck and listed also for Merck, thus making for duplication of products. The third is Medrol (methyl prednisolone) which is a molecular modification of prednisolone.

Three are of foreign origin:

Orinase: Oral diabetic drug secured by license from German firm, Hoechst.
Pamine bromide: Brand of scopolamine methylbromide. Scandinavian origin.
Pyrrolazote: An ethyl phenothiazine. Phenothiazines are of French origin.

Others listed are as follows:

Halotestin: Derivative of methyltestosterone. Upjohn has patent.
Orthoxine (methoxphyenamine): An antiasthmatic.
Plazmoid: Injectable gelatin used as blood plasma extender. Old product.
Cardrase (Ethoxlamide): A diuretic.
Dipaxin: Anticoagulant.
Cer-O-Cylin potassium: Penicillin O (structural variation on penicillin).
Polykol: Another laxative.
Vitamin K analog: One of several brands of vitamin K.

NOTE.—As compared with companies already mentioned, the Upjohn laboratories appear to have made some real contributions to the drug arsenal against disease.

7. MERCK & CO.

Twenty-six products listed: Of these, seven relate to cortical steroids; they are: Cortone acetate—cortisone. Original synthesis done in Merck Laboratories and therapeutic use discovered at Mayo Clinic. Impetus for work came from Office of Scientific Research and Development which gave contract to Merck during World War II. Cortisone held to be natural product and not patentable.

Hydrocortisone acetate: Molecular modification of cortisone.
Hydrocortone TBA Susp.: Form of hydrocortisone.
Hydeltra TBA: Form of prednisolone introduced by Schering and listed under that company.
Hydeltra opthalmic solution: Another form of prednisolone.
Decadron: Molecular modification of prednisone. Product involved in interference proceeding with no one yet awarded patent.
Alflorone: Modification of cortisone.

The remaining products vary in importance but most of them stem from work in the Merck laboratories; they are:

Dibione: Vitamin B–12. Patents held by Merck.
Diuril: Important diuretic.
Inversine: Hypotensive.
Suavitil: Tranquilizer, Danish origin.
Leritine phosphate: Another form of Leritine.
Nalline HCL: Test and antidote for overuse of narcotics.
Darstine: Anticholinergic of Sharp & Dohme (not listed in 1959–60 Blue Book).
Cathomycin sodium: Brand of novobiocin (interference).
Mustargen HCL: Form of nitrogen mustard sold by many, cancer therapy.
Benemid: Used in treatment of gout, Merck development.
Urecholine: Cholinergic.
Benodane: Diagnostic testing agent, not a therapeutic.
Floropryl: Opthalmic drug.
Daranide: Internal treatment for eye disorders.
Olothorb: Digestant (not listed in 1959–60 Blue Book).
Aramine bitartrade: Raise blood pressure in acute hypotensive states, decongestant inhalant.
Dornovac: Enzyme preparation, decongestant inhalant.
Cogentin: Treatment of Parkinsonism.

EXHIBIT 228

THE DE HAEN NEW PRODUCT SURVEY "SINGLE CHEMICAL ENTITIES, 1949–58"

In the short time available, an examination has been made of the De Haen list of new "single chemical entities" developed in the drug industry for the period from 1955 through 1958. This is approximately half of the list and work is continuing.

About 181 items comprise the list covering the 1955–58 period. An examination of these permits the following general comments:

1. There is considerable duplication of items. For example, oleandomycin is listed four separate times, hydrocortisone is represented by three preparations, prednisolone by three preparations, Compazine by three peparations, etc.

2. There are many duplicate drugs in the list. That is, one company develops a promising item and other companies plunge in to develop a slight molecular modification and market it as their specialty.

For example, there are 6 phenothiazines, 9 anticholinergic drugs, 5 laxative preparations, 5 muscle relaxants, 10 steroid preparations, 6 antihistamines, 6 hypnotic drugs, etc.

3. The list includes products other than drugs; 11 of the 181 items are really diagnostic materials, such as various preparations for testing the urine, contrast media for X-ray examinations, etc.

4. A sizable number of the drugs listed are very minor variations of old preparations. For example, there are 2 iron salts listed in the 181 compounds from 1955 to 1958. Diethylstilbesterol is listed, as are preparations of penicillin, sulfa drugs, calcium, chloral, dihydrocodeine, nitrate, theobromine, etc. One compound, Levonor, is an old drug available for some years in such countries as Hungary, Sweden, and Denmark.

According to Mr. De Haen, of the 63 "new single chemical entities" introduced during 1959, 20 of them—or 31.7 percent—came from Europe or were marketed by firms in the United States which are owned abroad. Twenty-seven of the 63 were based on old products—either derivatives of previously known structures or new salts of old products. Adding 20 and 27, this leaves only 16 "new single chemical entities" which were not based on old products, left for the U.S. industry to have developed (Drug Trade News, Jan. 25, 1960, p. 16).

EXHIBIT 229

Nobel Prize winners in medicine and physiology, 1945–59

Year	Winner	Nationality (at time of award)	Nation of birth (where citizenship changed)	Reason for awarding prize	Research done at (or place where working on award date)
1945	Sir Alexander Fleming	British		Discovery of penicillin	London University.
	Sir Howard Florey	do		do	Do.
	Ernest Boris Chain	German		do	Do.
1946	Herman Muller	American		Discovery regarding hereditary changes or mutations produced by X-rays striking the genes and chromosomes of living cells.	Indiana University.
1947	Carl and Gerty Cori	do	Czechoslovakia	Discovery of the process in the catalytic metabolism of the glycogen, or animal starch.	Washington University (St. Louis).
	Bernardo Houssay	Argentine		Discovery of the significance of the hormone produced by the pituitary gland.	Institute of Biology and Experimenta Medicine (Buenos Aires).
1948	Paul Mueller	Swiss		Discovery of the insect killing properties of DDT	J. R. Geigy, A. G. Basle, Switzerland.
1949	Walter Hess	do		Discovery of how certain parts of the brain control organs of the body.	Zurich University's Physiological Institute.
	Antonio Monis	Portuguese		Discovery of a surgical technique that opened up new possibilities in the treatment of mental illnesses.	University of Lisbon.
1950	Philip Hench	American		Work in cortisone and ACTH, hormones which relieve rheumatoid arthritis.	Mayo Clinic.
	Edward Kendall	do		do	University of Minnesota and Mayo Foundation.
	Tadeus Reichstein	Swiss		do	Basle University.
1951	Max Theiler	American	South Africa	Development of 17–D vaccine against yellow fever	Rockefeller Foundation (Public Health Division).
1952	Selman Wakeman	do	Ukraine	Discovery of streptomycin	Rutgers University (Institute of Microbiology).
1953	Fritz Lipmann	do	Germany	Discovery of coenzyme A and its significance in the intermediary metabolism.	Harvard University and Massachusetts General Hospital.
	Hans Krebs	British	do	Discovery of citric acid cycle	Sheffield University, Sheffield, England.
1954	John Enders	American		Cultivation of the polio virus, free from harmful tissue components, in the test tube.	Harvard University (Enders).
	Thomas Weller	do		do	Harvard University (Weller).
	Frederick Robbins	do		do	Western Reserve Medical School (Robbins).
1955	Hugo Theorell	Swedish		Isolation of yellow enzyme and the splitting of it into its constituent parts (20 years previous), and additionally, the isolation of a whole series of enzymes over the years, with demonstration of their functioning.	Biochemistry Department of the Nobe Medical Institute.

1956	Dickinson Richards	American		Heart catheterization and research carried out by its means.	Columbia College of Physicans & Surgeons and Bellevue Hospital.
	Andre Cournand	do	France	do	Do.
	Werner Forssmann	German		do	Germany.
1957	Daniel Bovet	Italian	Switzerland	Discovery relating to synthetic compounds that inhibit the action of certain body substances and especially their action on the vascular system and the skeletal muscles.	Superior Institute of Health, Rome, Italy.
1958	George Beadle	American		Experiments with bread molds showed that genes tranmsit hereditary characteristics by continuous chemical reactions. Discovery concerning genetic recombination and the organization of the genetic material of bacteria.	California Institute of Technology.
	Edward Tatum	do		do	Rockefeller Institute.
	Joshua Lederberg	do		do	University of Wisconsin.
1959	Svero Ochoa	do	Spain	Research on basic chemistry of life and heredity, and discovery of enzymes for artificially producing some of the key substances of life, nucleic acids.	New York University.
	Arthur Kornberg	do		do	Stanford University.

EXHIBIT 230

MEMBERS OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION (AS OF JAN. 1, 1960)

Abbott Laboratories, North Chicago, Ill.
Agricultural Division, American Cyanamid Co., 30 Rockefeller Plaza, New York, N.Y.
Alcon Laboratories, Inc., Post Office Box 1959, Fort Worth, Tex.
Ames Company, Inc., Elkhart, Ind.
Armour Pharmaceutical Co., Prudential Plaza, Chicago, Ill.
Arnar-Stone Laboratories, Inc., 225 East Prospect Avenue, Mount Prospect, Ill.
B. F. Ascher & Co., Inc., 113 West 18th Street, Kansas City, Mo.
Ayerst Laboratories, Division of American Home Products Corp., 22 East 40th Street, New York, N.Y.
J. T. Baker Chemical Co., Phillipsburg, N. J.
Baltimore Biological Laboratory, Inc., Division of Becton, Dickinson & Co., 2201 Aisquith Street, Baltimore, Md.
Barnes-Hind Laboratories, Inc., 895 Kifer Road, Sunnyvale, Calif.
Barry Laboratories, Inc., 9100 Kercheval Avenue, Detroit, Mich.
Baxter Laboratories, Inc., 6301 Lincoln Avenue, Morton Grove, Ill.
Don Baxter, Inc., 1015 Grandview Avenue, Glendale, Calif.
The Blue Line Chemical Co., 302 South Broadway, St. Louis, Mo.
The Bowman Bros. Drug Co., Canton, Ohio.
Boyle & Co., 6855 East Cage Avenue, Bell Gardens, Calif.
Brayten Pharmaceutical Co., 3804 St. Elmo Avenue, Chattanooga, Tenn.
George A. Breon & Co., 1450 Broadway, New York, N.Y.
Brewer & Co., Inc., 67 Union Street, Worcester, Mass.
Bristol Laboratories, Inc., Syracuse, N.Y.
Brunswick Laboratories, Inc., 8671 South Vincennes Avenue, Chicago, Ill.
Buffington's Inc., 8 Sudbury Street, Worcester, Mass.
The C. M. Bundy Co., 329 Perry Street, Cincinnati, Ohio.
Burroughs Wellcome & Co. (U.S.A.), Inc., 1 Scarsdale Road, Tuckahoe, N.Y.
Carbisulphoil Co., 2917 Swiss Avenue, Dallas, Tex.
G. W. Carnrick Co., 20 Mount Pleasant Avenue, Newark, N.J.
The Central Pharmacal Co., Seymour, Ind.
Chatham Pharmaceuticals, Inc., 901 Broad Street, Newark, N.J.
Chicago Pharmacal Co., 5547 North Ravenswood Avenue, Chicago, Ill.
Ciba Pharmaceutical Products, Inc., Summit, N.J.
Cole Chemical Co., 3721–27 Laclede Avenue, St. Louis, Mo.
The Columbus Pharmacal Co., 330 Oak Street, Columbus, Ohio.
Commercial Solvents Corp., 260 Madison Avenue, New York, N.Y.
Crookes-Barnes Laboratories, Inc., Wayne, N.J.
Cutter Laboratories, Fourth and Parker Streets, Berkeley, Calif.
Davies, Rose & Co., Ltd., 22 Thayer Street, Boston, Mass.
The DePree Co., 130 Central Avenue, Holland, Mich.
Difco Laboratories, 920 Henry Street, Detroit, Mich.
Distillation Products Industries, Division of Eastman Kodak Co., 729 Ridge Road West, Rochester, N.Y.
S. F. Durst & Co., Inc., 5317 North Third Street, Philadelphia, Pa.
Endo Laboratories, Inc., 84–40 101st Street, Richmond Hill, N.Y.
Ethicon, Inc., Somerville, N.J.
Ferndale Surgical Division, the J. F. Hartz Co., 780 West Eight Mile Road, Ferndale, Mich.
Fine Chemicals Department, American Cyanamid Co., 30 Rockefeller Plaza, New York, N.Y.
First Texas Chemical Manufacturing Co., 1810 North Lamar Street, Dallas, Tex.
C. B. Fleet Co., Inc., 921–27 Commerce Street, Lynchburg, Va.
Flint Eaton & Co., 300 East Main Street, Decatur, Ill.
E. Fougera & Co., Inc., Post Office Box 73, Hicksville, N.Y.
Geigy Pharmaceuticals, Division of Geigy Chemical Corp., Post Office Box 430, Yonkers, N.Y.

Haack Laboratories, Inc., 1415 Southwest Harbor Drive, Portland, Oreg.
G. F. Harvey Co., Inc., 5–9 Wells Street, Saratoga Springs, N.Y.
Heyden Newport Chemical Corp., 342 Madison Avenue, New York, N.Y.
Hobart Laboratories, Inc., 900 North Franklin Street, Chicago, Ill.
Hoffmann-La Roche, Inc., Nutley, N.J.
Hyland Laboratories, 4501 Colorado Boulevard, Los Angeles, Calif.
Hynson, Westcott & Dunning, Inc., 1030 North Charles Street, Baltimore, Md.
Irwin, Neisler & Co., Box 1110, Decatur, Ill.
Jensen-Salsbery Laboratories, 21st and Pennsylvania Streets, Kansas City, Mo.
Johnson & Johnson, New Brunswick, N.J.
Kinney & Co., Inc., 1327 California Street, Columbus, Ind.
Knoll Pharmaceutical Co., 377 Crane Street, Orange, N.J.
Kremers-Urban Co., 141 West Vine Street, Milwaukee, Wis.
Lafayette Pharmacal, Inc., 522-26 North Earl Avenue, Lafayette, Ind.
Lakeside Laboratories, Inc., 1707 East North Avenue, Milwaukee, Wis.
Lederle Laboratories Division, American Cyanamid Co., Pearl River, N.Y.
Thos. Leeming & Co., Inc., 155 East 44th Street, New York, N.Y.
Eli Lilly & Co., Indianapolis, Ind.
Lloyd Bros., Inc., 1016 Mound Street, Cincinnati, Ohio.
Lloyd, Dabney & Westerfield, Inc., 3941 Brotherton Road, Cincinnati, Ohio
Magnus, Mabee & Reynard, Inc., 16 Desbrosses Street, New York, N.Y.
Mallard, Inc., 3021 Wabash Avenue, Detroit, Mich.
Mallinckrodt Chemical Works, Second and Mallinckrodt Streets, St. Louis, Mo.
Maltbie Laboratories Division, Wallace & Tiernan, Inc., 240–250 High Street, Newark, N.J.
Paul Maney Laboratories, Inc., 402 First Street SE., Cedar Rapids, Iowa
The S. E. Massengill Co., Bristol, Tenn.
McNeil Laboratories, Inc., 2900 North 17th Street, Philadelphia, Pa.
Mead Johnson & Co., Evansville, Ind.
Medical Arts Supply Co., Inc., 710 Fourth Avenue, Huntington, W. Va.
Merck & Co., Inc., 126 Lincoln Avenue, Rahway, N.J.
Merck Chemical Division, Merck & Co., Inc., 126 Lincoln Avenue, Rahway, N.J.
Merck Sharp & Dohme, Division of Merck & Co., Inc., 640 North Broad Street, Philadelphia, Pa.
The Wm. S. Merrell Co., Cincinnati, Ohio
The National Drug Co., 4665–4685 Stenton Avenue, Philadelphia, Pa.
NYQ Chemical Division, S. B. Penick & Co., 100 Church Street, New York, N.Y.
Nion Corp., 1001 North McCadden Place, Los Angeles, Calif.
Nordon Laboratories, Box 1227, Lincoln, Nebr.
The Norwich Pharmacal Co., Norwich, N.Y.
The P. J. Noyes Co., Lancaster, N.H.
Organon, Inc., 20 Main Street, Orange, N.J.
Ortho Pharmaceutical Corp., Raritan, N.J.
Parke, Davis & Co., Detroit, Mich.
S. B. Penick & Co., 100 Church Street, New York, N.Y.
Chas. Pfizer & Co., Inc., 11 Bartlett Street, Brooklyn, N.Y.
Pitman-Moore Co., Division of Allied Laboratories, Inc., Post Office Box 1656, Indianapolis, Ind.
Wm. P. Poythress & Co., Inc., 16 North 22d Street, Richmond, Va.
Raymer Pharmacal Co., northeast corner Jasper and Willard Streets, Philadelphia, Pa.
Rexall Drug Co., 8480 Beverley Boulevard, Los Angeles, Calif.
A. H. Robins Co., Inc., 1407 Cummings Drive, Richmond, Va.
William H. Rorer, Inc., 4865 Stenton Avenue, Philadelphia, Pa.
Rystan Co., Inc., 7 North MacQuesten Parkway, Mount Vernon, N.Y.
Sandoz Pharmaceuticals, Division of Sandoz, Inc., East Hanover Labs., Route 10, Box 11, Hanover, N.J.
SchenLabs Pharmaceuticals, Inc., 350 Fifth Avenue, New York, N.Y.
Schering Corp., 60 Orange Street, Bloomfield, N.J.
Schiefflin & Co., 16 Cooper Square, New York, N.Y.
The Schuemann-Jones Co., 2134 East Ninth Street, Cleveland, Ohio
G. D. Searle & Co., Post Office Box 5110, Chicago, Ill.

Sherman Laboratories, 5031 Grandy Avenue, Detroit, Mich.
Smith-Dorsey, Division of the Wander Co., 233 South 10th Street, Lincoln, Nebr.
Smith Kline & French Laboratories, 1530 Spring Garden Street, Philadelphia, Pa.
Smith, Miller & Patch, Inc., 902 Broadway, New York, N.Y.
E. R. Squibb & Sons, Division of Olin Mathieson Chemical Corp., 745 Fifth Avenue, New York, N.Y.
Standard Pharmacal Co., 847 West Jackson Boulevard, Chicago, Ill.
G. S. Stoddard & Co., Inc., 295 Lafayette Street, New York, N.Y.
R. J. Strasenburgh Co., Post Office Box 1710, Rochester, N.Y.
Strong, Cobb Arner, Inc., 2654 Lisbon Road, Cleveland, Ohio
The Stuart Co., 3360 East Foothill Boulevard, Pasadena, Calif.
Surgical Products Division, American Cyanamid Co., 30 Rockefeller Plaza, New York, N.Y.
Sutliff & Case Co., Inc., 201 Spring Street, Peoria, Ill.
Texas Pharmacal Co., Post Office Box 1659, San Antonio, Tex.
The Tilden Co., New Lebanon, N.Y.
The Upjohn Co., Kalamazoo, Mich.
U.S. Vitamin & Pharmaceutical Co., 250 East 43d Street, New York, N.Y.
The Vale Chemical Co., Inc., 1201 Liberty Street, Allentown, Pa.
VanPelt & Brown, Inc., 1322 East Main Street, Richmond, Va.
Walker, Corp. & Co., Inc., Post Office Drawer 1320, Syracuse 1, N.Y.
Walker Laboratories, Inc., Bradford Road, Mount Vernon, N.Y.
Wallace Laboratories, 2 Park Avenue, New York, N.Y.
Wallerstein Co., Inc., Wallerstein Square, Mariner's Harbor, Staten Island, N.Y.
Wampole Laboratories, Division of The Denver Chemical Manufacturing Co., 35 Commerce Road, Stamford, Conn.
Warner-Chilcott Laboratories, Division of Warner-Lambert Pharmaceutical Co., 201 Tabor Road, Morris Plains, N.J.
Warren-Teed Products Co., 582 West Goodale Street, Columbus, Ohio
White Laboratories, Inc., Kenilworth, N.J.
Whittier Laboratories, Inc., 2101 Dempster Street, Evanston, Ill.
The Wilson Laboratories, Division of Wilson & Co., Inc., 4221–4225 South Western Avenue Boulevard, Chicago, Ill.
Winthrop Laboratories, Division of Sterling Drug, Inc., 1450 Broadway, New York, N.Y.
Wyeth Laboratories, Division of American Home Products Corp., Post Office Box 8299, Philadelphia, Pa.
The Zemmer Co., Inc., 231 Hulton Road, Oakmont, Pa.

EXHIBIT 231

CORPORATE EARNINGS RESEARCH SERIES

STANFORD RESEARCH INSTITUTE, MENLO PARK, CALIF, SEPTEMBER 1959

New-type comparative financial analysis of a major industry. Carefully compiled earnings and other key yardsticks for 33 industries. Comparable data for principal companies in industry. Planning capital expenditures. For corporate managers and staffs in appraising own company's and industry's performances.

On the dynamic industrial economy of America, the relative profitability and growth of companies and industries are subject to marked and continual change. Accordingly, the managing of corporate assets and the planning of capital expenditures require extensive and thoroughly diagnosed financial information. Corporate managers are finding it increasingly essential to have specific and accurate answers to such questions as:

How does the performance of our company compare with the performances of the other leading firms in our industry?

What is our relative sales growth? Capital expansion? Profitability?

How does our industry's performance compare with the performances of other major American industries?

How does our industry's return on investment and its growth in sales and capital compare with those of other major industries?

What significant changes are taking place within our industry?

THE CORPORATE EARNINGS RESEARCH SERIES

Specific answers to these and other questions are indispensable. But specific answers can be drawn only from factual information and intensive analysis. Comprehensive and consistently compiled financial data have been developed for 150 companies and 33 primary industries to meet these requirements of management. Stanford Research Institute plans to undertake further research in the field of industrial finance. The already compiled information covers nearly 25 years and provides financial yardsticks that measure the comparative earnings, sales, and other key factors in the financial performances of companies and industries. These financial yardsticks make possible comparative studies that supply corporate managers with—

1. An examination of the long-run record and basic changes in the earnings and financial experience of their industry.
2. A comparative analysis of the past and present performances of their industry relative to those of other major American industries.
3. A comparison of the financial record of major corporations in their industry in terms of the industry's composite experience.

THE U.S. CHEMICAL INDUSTRY

The first study in the corporate research earnings series is "The U.S. Chemical Industry: Its Comparative Earnings Performance." The study includes five basic features:

Executive summary

A succinct statement summarizes the most important conclusions of the 135-page study.

Methodology

Analytical procedures are described in detail so that corporate research staffs may check the information and undertake their own further analyses.

Comparative analysis

The study compares the composite growth and earnings performance of the major chemical corporations with the composite experience of the largest companies in 32 other major U.S. industries. This comparative analysis is supported extensively by charts and tables which provide specific details. For example, the following table from the study shows the relative average earnings of the chemical industry and of 32 other major industries through the 1953–57 period.

Comparative industry earnings rates on total capital

[Average rate 1953–57]

	Percent
Aircraft	21.3
Proprietary drugs	20.5
Automobiles	19.5
Apparel and accessory chains	14.6
Ethical drugs	14.6
Nonferrous metals	14.4
Corn products	13.1
Chemical, including Du Pont	13.0
Auto parts and accessories	13.0
Building materials	12.8
General industrial machinery	12.4
Oil	12.1
Glass containers	12.0
Toilet preparations and soap	11.9
Electrical supplies and equipment	11.8
Copper	11.5
Packaged foods	11.4
Paper and allied products	11.3
Mail order houses	10.9
Steel	10.7
Grocery chainstores	10.3
Rubber	10.2
Chemical, excluding Du Pont	10.1
Dairy products	9.6
Cigarettes	9.0
Radio and television	8.8
Grain mill products	8.1
Limited-price variety	8.1
Metal containers	8.1
Department stores	7.9
Distilling	6.2
Agricultural machinery	5.9
Textile fabrics	5.7
Meat packing	4.0

Source: Stanford Research Institute.

Graphic material

Graphs and tables provide a comparison of the growth and earnings of seven major chemical corporations. This analysis constitutes the basis for a fuller appraisal of the composite experience of the industry, in addition to developing information important in appraising the performance of the individual companies. The chart which shows the relative growth in sales of the seven companies from 1947 to 1957, is one of the many graphic comparisons of individual company performance contained in the study.

Economic analysis

A summary economic review analyzes the product anatomy of the chemical industry. This analysis concerns primarily the postwar output growth of the major industrial chemicals. The study also provides information on the consumption pattern and other aspects of the supply-demand situation for each chemical.

CONTRIBUTIONS TO MANAGEMENT

This financial analysis of the chemical industry, with its supporting data, is designed to assist corporate managers in—

Judging the progress of their company and probing weak and strong points.

Assessing growth in sales, level of return on capital, profit margins, depreciation, and other important factors.

Planning with more precision capital expenditure and expansion programs.

Appraising the basic changes in and the comparative performance of their industry.

The study provides the corporate executive with a basis for solving these and other vital managerial problems. Analytical staff members will also find the study useful in undertaking further financial analyses.

The chemical industry study may be obtained from Stanford Research Institute for $1,500.

Seven major chemical companies comparative postwar growth in sales

[Annual average rate 1947–57]

	Percent
Monsanto (Lion oil—1955)	15.9
Dow	14.3
Union Carbide	10.0
Chemical industry sample (excluding Du Pont)	9.9
American Cyanamid	9.7
Du Pont	9.3
Hercules	7.2
Allied Chemical	7.1

Source: Stanford Research Institute.

EXHIBIT 232

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 20, 1959.

REPORT TO THE PMA MEMBERSHIP ON RESEARCH AND DEVELOPMENT ACTIVITY IN THE PHARMACEUTICAL INDUSTRY

At the suggestion of the National Institutes of Health, the Pharmaceutical Manufacturers Association has conducted a survey on industry expenditures for research and development in 1958 and 1959, contributions to medical and related schools, hospitals, etc., in 1958 and 1959, and numbers of chemicals and other substances tested for medical research purposes in 1958. The following report is offered as a source of basic information for your use; it is not suitable for general distribution without appropriate interpretation and enlargement.

I. *Support of research and education.*—In the research expenditures study, the definition of research and development used was identical to that employed by the undersigned in the 1957 survey, which resulted in a total reported expenditure of $127 million for the calendar year 1957. This definition follows:

"For the purposes of this survey, the term 'drug or medical research and development' includes basic and applied research activities and development carried on or supported in the medical, biological, chemical, and pharmaceutical sciences, and in related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding human diseases or in improving human health.

"Activity in pursuit of the following objectives is included:

"(1) Planned search for new knowledge, whether or not the search has reference to a specific application.

"(2) Application of existing knowledge to problems involved in the creation of a new product or process, including work required to evaluate possible uses.

"(3) Application of existing knowledge to problems involved in the improvement of a present product or process.

"For practical purposes, any scientific or technical activity which could result in a new drug, as defined in the Federal law, would certainly be considered research and development. Chemical synthesis of substances which might become drugs would be included in this definition, and all clinical evaluation of new or old drugs would be.

"The question, 'When does this development end and production begin?' is often asked. If the primary objective is to make further improvements on the product or process, then the work comes within the definition of research and development. If, on the other hand, the product or process is substantially 'set,' and the primary objective is to develop markets or to do preproduction planning, or to make engineering changes in production equipment, then the work is no longer research and development. Routine quality control activities are not to be

included in this survey; figures or estimates in development of quality control methods are to be included, if readily available."

Definite responses from 59 member firms have been received, representing more than 92 percent of the total ethical pharmaceutical business of the PMA membership. When calculated to represent 100 percent, the total industry expenditures for research and development, and for support of medical education, are given below. We believe these figures to be quite accurate.

	Estimated or budgeted	
	1958	1959
(1) Amount spent within companies for research and development	$156,600,000	$174,700,000
(2) Amount spent outside companies for research and development (contracts or grants to universities, hospitals, etc., for specific projects)	13,400,000	15,300,000
Total for research and development	170,000,000	190,000,000
(3) Unrestricted grants, contributions, gifts to schools, hospitals, etc., for unspecified purposes, not included above	5,260,000	5,950,000
(4) Contributions or gifts to organizations which in turn support medical and related schools (not included above)	1,900,000	2,000,000
Total industry expenditures for research and development, and for medical and related education	177,160,000	197,960,000

Of the total expenditures cited here, $20,560,000 went in 1958 to medical and related schools, hospitals and similar organizations, as the pharmaceutical industry's support of these institutions as such, and for support of research being conducted in them.

II. *Research materials studied.*—In the study of chemicals and other substances obtained and tested during 1958, each member company was asked to furnish, on a confidential basis, an estimate of the number of chemicals, compounds, mixtures, filtrates, or other substances obtained, prepared, extracted, or isolated for a medical research purpose, and subjected to biological tests or screens. Materials obtained from outside the company were included. Routine in vitro screens were omitted, but all materials subjected to significant in vivo procedures, tissue culture studies, pharmacological or biochemical workups, were reported. In addition, the number of chemicals or other substances tested clinically (in humans) during 1958 was reported.

For the entire PMA membership, 114,600 chemicals, mixtures, filtrates, etc., were obtained or prepared, and were tested biologically or pharmacologically, as defined above. In the clinical field, 1,900 substances were tested in humans, in 1958.

In addition to the 114,600 chemicals and other substances reported here, a great many more materials of all kinds, including samples of plants and of soil from all parts of the world, were obtained and subjected to routine preliminary screens to ascertain if they possessed any physiological activity.

An important phase of health research, which is sometimes overlooked by those outside the field, is the cost involved in preparing, isolating, or otherwise obtaining large numbers of chemicals, antibiotic filtrates, and other substances for testing, in the hope of finding a therapeutically useful material. Some experts estimate that about one-half of the total research expenditure must go to support the work of organic chemists, biochemists, and other scientists in systesizing, purifying, modifying, and preparing suitable substances for subsequent physiological tests.

To obtain only one drug for clinical investigations, 60 substances on the average were prepared and biologically tested in 1958. Thus, many materials must be carefully tested in animals before one is found suitable for further investigation in the clinic.

Now, this does not mean that every drug studied in the clinic will eventually reach the market. Instead, it must be remembered that 44 completely new chemicals were marketed by the industry during 1958, according to the yearly report of a reliable marketing consultant. Of these 44 new drugs, 16 came from non-U.S. sources, and 6 represented minor modifications of older drugs. Thus it can be said that the expenditures during previous years of the U.S. pharmaceutical industry in research and development resulted in market introduction in 1958 of 20 to 30 really new drugs. Each new drug marketed can be regarded

as having had $6 million in total industry research and development expenditures as its share of the combined research effort. Of course, only a few of the 44 really new chemicals or substances marketed during 1958 will become outstanding commercial successes, although it must be recognized that practically all of them represent successes in research or medical science.

The costs of research and development are great. Research administrators estimate that the simplest antibiotic filtrate requires from 60 to 200 skilled man-hours for preparation and testing. To synthesize and test a new chemical, some 400 man-hours are required, as a minimum. These rough figures hold only if the biological tests are disappointing: that is, if negative or medically useless results are obtained. If the new substance looks promising, research time skyrockets, because many more tests must then be run.

Some industry accountants use a figure of $10 per man-hour for ordinary research time costs, but it must be remembered that scientific work cannot be categorized and costs estimated in a simple fashion. To build and maintain an effective research organization requires a substantial investment; each scientist of Ph. D. training or its equivalent, with necessary technical help, laboratory animals, equipment, supplies, and administrative services, costs a pharmaceutical house about $40,000 per year. This figure is estimated at various levels by organizations of differing size and scope; some companies set the cost at $30,000 per responsible scientist, others at $50,000.

Even though each significant research project represents a sizable financial obligation, which is not entered into lightly, the ethical pharmaceutical industry continues to invest ever-increasing amounts to discover ways of curing and preventing disease. These sums, $127 million in 1957, $170 million in 1958, and at least $190 million for 1959 will no doubt become even larger in future years. The financial commitment is great, but so is the possible reward in commercial return and, above all, in the benefit to the public health.

KARL BAMBACH,
Executive Vice President.

EXHIBIT 234

[From Drug and Cosmetic Industry, January 1958]

PRICE DETERMINATION THEORY IN THE PHARMACEUTICAL INDUSTRY [1]

By Joseph D. McEvilla, Ph. D., Assistant Professor of Pharmacy Administration, University of Pittsburgh

Recently increased attention has been directed toward the pricing procedure of the pharmaceutical industry. Pricing policy, market structure, and the institutional nature of an industry making products for the professional use of those working in the health sciences must be very closely interwoven. This study examines these interwoven parts and their relationship to economic theory.

Economic theory provides a variety of concepts used by industry in the determination of price. These various theoretical situations range from perfect competition to pure monopoly. Within these two extremes there are numerous competitive arrangements applicable to the majority of American business institutions. The principles of oligopoly have a particular relevance to the pharmaceutical industry. The interfirm relationships that exist under this theoretical concept range from pure competition to perfect monopoly. Because of these various relationships, it is possible to construct theoretical conditions descriptive of almost any market situation.

Oligopoly includes, among others, the following basic principles. The market structure should contain a small number of sellers of comparable size and standing within the industry. These firms should produce a significant part of the total industry output. This significant part of total output, percentagewise, may be high or low depending upon the degree of concentration within the industry. Each leading firm within an oligopolistic market structure can directly influence price by its own acts. Further, each seller tries to estimate the output and price policy of his rival while at the same time considering the consequences of his own output and price policy on the entire market.

Oligopolistic market structures are of two general types: (1) Pure oligopoly, a market situation where the firms within the industry produce a standardized

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[1] Presented before the Fourth Pan-American Congress of Pharmacy and Biochemistry, Washington, D.C., November 1957.

product; and (2) differentiated oligopoly, a market structure where each firm within the industry differentiates its products from the products of every other firm composing the industry. This differentiation may be achieved by various means, among which may be style, package design, trade name, trademark, or patent.

The extent of concentration within the pharmaceutical industry is indicated by the fact that in 1956, 10 firms[2] had slightly more than 80 percent of total sales. The largest firm has 12.1 percent, the second largest firm had 11.9 percent of total industry sales. While the individual firm enjoys what at first seems a relatively small percent of total industry output, in an industry composed of 1,163 manufacturers where less than 1 percent of the firms enjoy over 80 percent of total annual industry sales, a recognizable degree of concentration is apparent.

Prior to World War II, a fraternal attitude of live and let live served as a modus operandi for the industry. If one firm developed an efficacious product within a certain field, the other firms were apt to avoid that field in their plans for research and product development. In the decade since the end of the war, this attitude has changed to one of intense competition.

In oligopolistic market structures such as this industry, the sales of all other firms within the industry are influenced by the prices charged by any one of the leading firms within the industry. The members of the industry are quick to recognize that increases in their prices, other than increases resulting from increased labor and raw material cost which would affect all members of the industry, reduces the quantity of goods they sell. Price cuts by any one member of the industry are quickly followed by like reductions by other members and result in no increase in total sales.

This concept of mutual dependency is quite evident within the pharmaceutical industry. In a survey of pricing methods of pharmaceutical manufacturers all respondents stated that they considered the price of a competing product of the same therapeutic classification when establishing the list price for a new product. Price fluctuations of specific products such as those which have occurred in the antibiotics, antihistamines, and steroids further exemplifies this recognition of interdependency. Additional evidence is provided by the statements of industry representatives. One such reply may be cited as typical. Manufacturer A stated they would not be likely to cut price if the rival price was within range of their own logical price.

This recognition of interdependency within the framework of oligopoly does not necessarily imply the existence of monopoly pricing. To a considerable extent, however, it does remove the uncertainty of action of rival firms when changes in price or price policy are contemplated. This helps to expalin both the long-run stability and the interfirm uniformity of price on a variety of specific products within any given therapeutic classification.

The pharmaceutical industry, consisting of more than a thousand firms, nevertheless is an industry with a relatively high degree of concentration in terms of total industry sales, share of the market, or asset valuation. Within the industry there is a small number of firms of comparable size and prestige. Individual products which enjoy medical acceptance, are produced by one, two, or at most a few firms. This creates a market structure for the individual product ranging from monopoly, to duopoly, to oligopoly. Rarely, if ever, are there sufficient manufacturers of equal size and prestige to create a condition of either pure or perfect competition. When a small number of manufacturers produce a differentiated product which may not be a perfect substitute for the other, for any one producer to neglect the effect his price will have on the others is extremely shortsighted.

Under conditions of oligopoly, demand has had various treatments in the literature. In 1939 R. L. Hall and C. J. Hitch in England and Paul M. Sweezy in America independently advanced the theory of the kinked demand curve.[3] Each proposed the theory that the demand curve of a firm operating within an oligopolistic market was kinked at the existing price. Sweezy states that changes in demand will not tend to affect the price at which the "kink" occurs as such changes affect the elasticity of the demand curve on each side of the "kink" in an asymmetrical manner. In other words, increases in demand will

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[2] Eli Lilly & Co.; Parke, Davis & Co.; Upjohn Co.; Wyeth; Merck-Sharp & Dohme; E. R. Squibb; Abbott Laboratories; Smith, Kline & French; Lederle Laboratories; Pfizer.

[3] Hall and Hitch, "Price Theory and Business Behavior," Oxford Economic Papers, No. 2 (May 1939), pp. 12–45; and Sweezy, "Demand Under Condition of Oligopoly," the Journal of Political Economy, vol. XLVII (August 1939), pp. 568–573.

tend to produce a price rise, however, as price rises the quantity demanded will increase at a smaller ratio for each price increase. The opposite effect will take place under conditions of decreased demand. These opposing forces tend to create a point of stability at the prevailing price, regardless of the increases or decreases in demand. He further states that in the cyclical behavior of oligopoly price, we would expect: (1) Prices to increase in periods of business upturn; (2) price stability and strong resistance to any downward pressure in times of recession and depression; and (3) that the longer the downward trend in business occurs the less truthworthy list prices become. It might also be stated that as interfirm competition increases in intensity, the less list prices reflect the actual or true price regardless of demand conditions.

Hall and Hitch state that businessmen seek a full cost method of price determination. They desire to establish and maintain a price that will cover average cost. Since the average producer has little if any knowledge of his marginal revenue or marginal cost, these two factors which find extensive use in economic analysis are disregarded. In view of this, the price is set at a point that will cover average cost, plus allowance for profit, at a predetermined or anticipated output. Increases or decreases in demand will shift the kink to the right or left, but price will remain unchanged. There are two exceptions to this: (1) If the demand decreases to a large extent and remains depressed for a prolonged period of time, price will be reduced in an effort to maintain output; (2) if the average cost curve of all firms shifts by the same amount due to increases or decreases in factor prices, this may result in a revaluation of the full cost price.

In the pharmaceutical industry a sharp and prolonged decline in demand will usually result from a competing product with superior therapeutic effect gaining acceptance. In such a case, production of the product with reduced demand may be discontinued and all promotional effort cease.

In 1947 Professor Stigler challenged the validity of the theory of the kinked demand curve.[4] This was done by empirical investigation of the prices of a number of products produced under conditions of oligopoly. However, none of the products investigated reached the consumer only by the selection of physicians or dispensing by pharmacists.

The kinked demand curve may have a distinct application to the pharmaceutical industry. Manufacturers of prescription products must be aware not only of the price charged to pharmacists but also of the final price to consumers. Since small changes in the price to retail pharmacists will have a negligible effect on the price charged ultimate consumers, there is little incentive to make small changes in price. This aids in explaining the stability in price over a wide range of demand conditions.

The answers supplied by members of the pharmaceutical industry add support to the theoretical concepts outlined above. In answer to the question as to whether prices or output would be adjusted in the event of an inventory buildup, it was always stated that output would be reduced while price would remain constant. This would tend to indicate that the inventory theory of price determination has little application to the pharmaceutical industry.

From the above it can be seen that the demand curve in a differentiated oligopoly becomes relatively unimportant to the individual firm. There is a large degree of monopolistic exploitation of the industry demand curve. The demand curve for each firm becomes a fractional part of the industry demand curve. Oligopolists tend to establish a price at a figure which will net a "fair" return over a wide range of demand conditions. This pricing policy obviously is not based upon short-run marginal analysis. An illustration of such pricing may be observed in the price of a broad-spectrum antibiotic produced by a leading manufacturer. Sales of this particular product declined 52 percent in a 3-year period while price remained stable. The drug industry may be characterized by a great deal of longrun price stability. Many of the official preparations have had periods of price stability extending longer than a decade. In these periods of price stability, demand conditions have in most cases varied in extremes depending upon the product investigated.

Price rigidity is an essential aspect of normal oligopolistic price strategy. Changes in list price rigidity are brought about by changes in credit terms, invoice discounts or cumulative discounts, free goods or bonus goods. These changes enable the firm to adjust to some extent to variations in external circumstances while maintaining the status quo of the list price. They also

[4] George J. Stigler, "The Kinky Oligopoly Demand Curve and Rigid Prices," the Journal of Political Economy, vol. LV (1947), pp. 432–449.

serve a second function as tools of tactical maneuvers in an enemy's territory without the dangers of a major price conflict.

Price determination by a fixed or variable markup added to cost, usually results from uncretainty of demand conditions. When demand is uncertain, any calculation of marginal revenue becomes extremely hazardous. A markup which will cover basic average costs, neglecting any short-run variations in average fixed costs, is usually used. Price is then determined by short-run average variable costs and if such costs are constant, some degree of marginal cost analysis may be used. However, it is doubtful if average variable costs are constant within the pharmaceutical industry.

In determining price, pharmaceutical manufacturers tend to use a variable markup added to cost. In establishing a list price, direct and indirect selling costs plus a variable weighted factor—research—are added to basic production costs. When questioned regarding pricing procedure, one manufacturer stated "the list price is definitely based upon a percentage of markup from cost." Another manufacturer stated, "for products in the medium priced prescription range, roughly three to four times the cost of manufacture is taken as the starting point in the calculation of list price. With less costly items this differential is greater and vice versa." In answering this question, another manufacturer stated, "The circumstances that influence price vary greatly from product to product. A simple formula is impossible to use since the factors involved include such things as research and development costs, prices of competitive products, production and material costs, and anticipated future economies of production. Any one or a combination of the above factors may be dominant in determining price. Since varying weights are assigned to each factor in determining the markup added to product costs, a definite formulation of price is impossible to be stated."

From these examples, which are representative of all answers received, it is evident that manufacturers of ethical pharmaceutical products use an oligopolistic method of price determination. The demand curve, while estimated, is only a poor estimate of possible sales by the individual firm and is largely neglected in determining price. Marginal analysis, if used, is used in such a way as to be obscured by the overall method of full cost or cost-plus price determination.

Oligopolistic market structures emerge for various reasons among which are: (1) A dominant position in the industry is secured by a few firms from the time of its origin, (2) the initial atomistic structure of the industry with a few firms gaining eventual control by normal growth or merger, and (3) the development of a product which meets with success in a given area may establish a firm in a dominant position within a well-defined area of production.

Some form of price leadership may result from any one of the above conditions for the emergence of oligopoly.

Except for the official preparations, the role of the dominant firm, as described by Professor Stigler, does not exist in the pharmaceutical industry.[5] In trying to apply this concept to firms within the industry, it can be found only by limiting "dominance" to one product. When this is done, several such firms emerge. Each therapeutic classification of pharmaceutical products tends to have a dominant firm which serves as a price leader for the classification. Several illustrations of this type are available. The field of antibiotics, steroids, and anthihistamines may be mentioned to cite a few.

Another type of price leadership is that of the barometric firm. This type of firm has had very little treatment in economic literature. Such a firm has however been described as one that "Commands adherence of rivals to his price only because and to the extent that his price reflects market conditions with tolerable promptness." [6] This type of leadership, based upon past performance, develops out of the historical and institutional features of the industry.

There are two firms within the pharmaceutical industry which may be of the barometric type, Parke, Davis & Co. and Eli Lilly & Co. Each of these firms has had a favorable profit picture and each has had its share of firsts. If either of these firms occupied the position of partial monopolist, the remaining firms would have no choice but to accept any price they would set on a product. True dominant firm price leadership is a form of monopolistic pricing. Such is not the case in the pharmaceutical industry. These two firms are of the barometric type, acceptance of their prices being based upon their past history of correctly determining costs and future market events. Rival firms

[5] Ibid.

are free to accept or reject their price, each acting independently. If either firm were a partial monopolist, such would not be the case.

The price leadership which either of these firms may exercise should not be considered price control. The latter is a definite symptom of monopoly, while the former may be considered a condition of rather strong competition within the industry.

This discussion of the economic theory of oligopoly and oligopolistic rationalization of mutual dependency is helpful in explaining the relationship between firms and the price policies of firms within the American pharmaceutical industry. The theory of oligopoly, with a degree of price leadership in certain areas, is characteristic of market structures where there are only a few sellers of equal strength.

While the pricing practices of firms within the industry help to validate the theory of oligopoly and to some extent give cause for additional investigation into the theory of the kinked demand curve, pricing practices or oligopoly theory as antecedent should also help to prove that this type of market structure with its mutual effect of action and reaction does not necessarily result in monopoly pricing.

EXHIBIT 268

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 18, 1960.

Hon. ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust and Monopoly,
Senate Office Building, Washington, D.C.

DEAR SENATOR KEFAUVER: The following is the statement which Dr. Austin Smith indicated would be forthcoming (p. 4170, transcript, your subcommittee hearing on the drug industry, April 20, 1960) with regard to industry development of penicillin. This is quoted from "Economic Report on Antibiotics Manufacture" Federal Trade Commission, June 1958:

"In all, 22 antibiotics facilities were authorized under the wartime program, including the 6 initial units financed by the Government. The 20 companies authorized to participate in the World War II antibiotics program, and the plants covered by the authorizations, are listed in table 3. These facilities included 20 penicillin production units, 1 penicillin research unit, and 1 streptomycin pilot plant. These facilities were not, in most cases, entire plants. Some of them merely represented additions to plants already experimenting with antibiotics production. From such data as are available, it appears that the total estimated cost of wartime plants to be built with private funds amounted to $22,640,670. As previously indicated, the Government expended $7,577,697 for plants. Thus, total of private and public funds authorized for new plant expenditures during World War II was $30,218,367. Of this amount, funds contributed initially by the Government represented about 25 percent. This intensive plant construction program proceeded despite the general belief that penicillin production by chemical synthesis would soon replace the use of molds. Instead, it was found possible to produce penicillin in great volume through the growth of molds."

Sincerely,

WM. KLOEPFER, Jr.

EXHIBIT 269

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 18, 1960.

Hon. ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust and Monopoly,
Senate Office Building, Washington, D.C.

DEAR SENATOR KEFAUVER: The following is the material which Dr. Austin Smith indicated would be furnished for the record at page 4176 in the transcript of the hearings of your subcommittee on the drug industry on April 20, 1960:

Accusation: $3,006,000 spent by one company in October 1957 to send an assorted sample package to 150,000 M.D.'s.

Fact: $108,000 spent to send it to only 6,000 newly practicing M.D.'s.

Accusation: $297,849 spent by another company on circulars and samples sent to 150,000 M.D.'s in December 1959.

Fact: $132,255 spent; number of physicians addressed on a given piece ranged from 1,700 to 141,000.

Accusation: $296,034 spent by another company on December 1959 mailings.
Fact: $65,902 spent.
Accusation: $265,808 spent by another company in December 1959.
Fact: $100,000 spent on all mailings to both GP's and Ob–Gyn's.
Accusation: $149,566 spent by another company on mail of the type reaching the accusing witness in December 1959.
Fact: $35,220 spent on mail of the type reaching him.

Sincerely,

WM. KLOEPFER, JR.

EXHIBIT 279

WCD Offers Druggists Personal Press Release Service to Offset Harmful Drug Publicity

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Here's How to Counteract Effects of Kefauver Hearings In Your Area

Reproduced in the box on this page is the first of a series of press releases being provided by WEST COAST DRUGGIST as a service to its readers.

Similar press releases will be provided each month during the continuation of the Kefauver drug pricing and related investigations.

You saw the hurtful headlines —hurtful to you and your colleagues in the drug industry — which were generated in newspapers by the allegations of the Kefauver investigation into steroid drugs in early December. Kefauver has scheduled a resumption of hearings, about January 15th.

It is to be expected that, once again, the newspapers will be black with headlines insinuating that the pharmacist "is cheating the public."

The press releases which WEST COAST DRUGGIST will provide for you during this investigation can be very helpful in countering some of the resultant bad publicity.

Procedure

Here is the procedure to follow to ensure publication of these releases in your local newspaper:

1. Retype the press release on a sheet of white paper, double-spacing the copy. If you cannot retype the story, just cut out the box at the right and use it as it is. It is far better, however, that the story be completely retyped as already described.

2. Fill in your name in the blank spaces provided. Use your full name in the first paragraph; and, thereafter, only your last name.

3. Hand-carry the release to your local newspaper editor. (If you haven't the time to take it to the newspaper office, you can mail it; but this is far less effective in ensuring publication.)

If you will retype the release and deliver it personally to the newspaper editor, the chances of its being printed are fairly good because it carries the weight of a "local story" and quotes a local source.

Most weekly papers have only one "editor." He is the man to see. Daily newspapers have a number of "editors" and the best one to see on a daily is the "city editor," or his assistant.

If you know the "chief editor" of your daily newspaper personally, by all means drop by to see him. But, give the news release to the "city editor." He is the man responsible for local news and he may be displeased if he thinks you went over his head.

PRESS RELEASE

(For Immediate Use)

Americans today are the world's healthiest people largely because of thousands of failures suffered in medical research, Pharmacist _____ (name of pharmacist) of this city said here today.

"This may sound like a strange idea," Pharmacist _____ (name) asserted, "but, nevertheless, it is true."

What is not generally realized by the lay public, he pointed out, is that for every major drug discovery the pharmaceutical industry writes off hundreds, even thousands of failures. The pharmaceutical industry, in fact, considers itself fortunate if it develops one useful drug out of every 1,000 chemical compounds it investigates, Pharmacist _____ added. (name)

To some, the local pharmacist said, this may sound wasteful in manpower and money. The fact remains, however, that screening and testing thousands of different compounds is often the only way of finding a drug which may revolutionize the medical treatment of some hitherto fatal disease and save thousands of lives.

As an example, Pharmacist _____ (name) cited the case of a well-known antibiotic, which was discovered only after scientists had screened and tested 1,000,000 soil samples. Two and one-half years and more than $4,000,000 was spent on the project. Today, however, that antibiotic is one of medicine's most formidable battlers against bacterial disease.

"Americans have the most effective and potent medicines in the world today, simply because our medical re-

(Turn to page 24)

PRESS RELEASE

(From page 7)

searchers are willing to face failure after failure in their attempts to find new drugs to alleviate illness," the local pharmacist asserted.

"For this reason," he added, "a drug which has newly come on the market is often somewhat expensive. Penicillin, for instance, cost $900.00 per billion units in 1946 when it was first developed. Today, the cost of penicillin has been reduced to something like 90 cents per billion units."

Another germ fighter, which is newer on the market than penicillin, costs about 50 cents per capsule at retail, the pharmacist said. This cost reflects the vast amount of time and money which the pharmaceutical industry expended to find and develop the drug. However, $15.00 worth of this medicine is sufficient to clear up a case of pneumonia in about a week. Twenty years ago, pneumonia killed one out of three cases; if you survived, it cost five weeks in the hospital plus a long convalescence at home. Medical bills ran up as high as $300 or $400, Pharmacist _____ (name) said.

"Medical research," the local pharmacist concluded, "is a complicated, time-consuming business filled with uncertainties and disappointments. It involves huge investments in laboratories and equipment and requires the efforts of thousands of highly trained scientists.

"But, today Americans live longer and stay healthier. If they do get sick, their illness often is shorter and their total medical bill is smaller.

"All of this can be had for only a few dollars worth of a miracle--a miracle discovered and produced by American pharmaceutical know-how," Pharmacist _____ (name) said.

EXHIBIT 280

[From Westlake Times, Feb. 3, 1960]

AMERICANS HAVE FINEST DRUGS IN WORLD TODAY

Americans today are the world's healthiest people largely because of thousands of failures suffered in medical research, Pharmacist Elton McGraw of Daly City said today.

"This may sound like a strange idea," McGraw asserted, "but, nevertheless, it is true."

What is not generally realized by the lay public, he pointed out, is that for every major drug discovery the pharmaceutical industry writes off hundreds, even thousands, of failures. The pharmaceutical industry, in fact, considers itself fortunate if it develops 1 useful drug out of every 1,000 chemical compounds it investigates, he added.

To some, the local pharmacist said, this may sound wasteful in manpower and money. The fact remains, however, that screening and testing thousands of different compounds is often the only way of finding a drug which may revolutionize the medical treatment of some hitherto fatal disease and save thousands of lives.

As an example, McGraw cited the case of a well-known antibiotic, which was discovered only after scientists had screened and tested 1 million soil samples. Two and one-half years and more than $4 million was spent on the project. Today, however, that antibiotic is one of medicine's most formidable battlers against bacterial disease.

"Americans have the most effective and potent medicines in the world today, simply because our medical researchers are willing to face failure after failure in their attempts to find new drugs to alleviate illness," the local pharmacist asserted.

"For this reason," he added, "a drug which has newly come on the market is often somewhat expensive. Penicillin, for instance, cost $900 per billion units in 1946 when it was first developed. Today, the cost of penicillin has been reduced to something like 90 cents per billion units."

Another germfighter, which is newer on the market than penicillin, costs about 50 cents per capsule at retail the pharmacist said. This cost reflects the vast amount of time and money which the pharmaceutical industry expended to find and develop the drug. However, fifteen dollars' worth of this medicine is sufficient to clear up a case of penumonia in about a week. Twenty years ago, pneumonia killed one out of three cases; if you survived, it cost 5 weeks in the hospital plus a long convalescence at home. Medical bills ran up as high as $300 or $400.

"Medical research," the local pharmacist concluded, "is a complicated, time-consuming business filled with uncertainties and disappointments. It involves huge investments in laboratories and equipment and requires the efforts of thousands of highly trained scientists.

"But, today, Americans live longer and stay healthier. If they do get sick, their illness often is shorter and their total medical bill is smaller.

"All of this can be had for only a few dollars' worth of a miracle—a miracle discovered and produced by American pharmaceutical know-how," McGraw concluded.

EXHIBIT 281

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 20, 1960.

Hon. ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust and Monopoly,
Senate Office Building, Washington, D.C.

DEAR SENATOR KEFAUVER: At page 4211 in the transcript of your subcommittee hearings on the drug industry you asked Dr. Austin Smith to provide for the record a summary of our survey of Food and Drug Administration enforcement actions, comparing our association's members' records with the rest of the industry. A copy of this summary is enclosed.

Sincerely,

WM. KLOEPFER, JR.

FDA LEGAL ACTIONS INVOLVING PMA MEMBERS

The attached table[1] lists all FDA legal actions involving PMA members, including their proprietary and vet drug products, for the years 1950 through 1959.

All were civil seizure actions, except two criminal cases—one each noted in 1954 and 1956. Cases are listed with dates of final adjudication for all years except 1958 and 1959. One case awaiting adjudication at the end of 1959 is included. All seizures were adjudicated on basis of default or consent decrees.

Notes are included to indicate unique characteristics of cases—for example, inert glandular seizures to clear up legal controversy, the *Lilly* test case on adequacy of directions, etc.

It is important to note that while PMA members account for production estimated to exceed 95 percent of the U.S. total, they were involved in only a tiny fraction of FDA cases.

Total number of FDA drug cases involving manufacturers adjudicated in 1950, 1951, and 1952 not available because statistics are confused. This was prior to enactment of Durham-Humphrey law, and total number of drug cases for 3 years include actions at retail level. Best informed estimate is that the total involving manufacturers was in excess of 200 for each of the 3 years. PMA members were involved in seven cases in 1950, six in 1951, and four in 1952. Following is tabulation of adjudicated drug manufacturer cases for subsequent years:

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[1] Supplied to the subcommittee; available at PMA on request.

	Seizures		Criminal cases		Injunction cases		Total cases
	Total	PMA members	Total	PMA members	Total	PMA members	
1953	163	5	35	0	5	0	203
1954	195	10	21	1	0	0	216
1955	155	8	14	0	3	0	172
1956	108	3	16	1	2	0	126
1957	120	4	14	0	5	0	139
1958	153	9	13	0	2	0	168
1959	140	8	23	0	3	0	166

EXHIBIT 282

APRIL 18, 1960.

Memorandum to: Paul Rand Dixon, counsel and staff director.
From: John M. Blair, chief economist.
Subject: Testimony of Dr. Austin Smith and Press Release of Pharmaceutical Manufacturers Association, February 24, 1960, on Concentration in the Drug Industry.

On February 24 I presented to the subcommittee a table entitled "Concentration of Production, 1958—Hormones, Diabetic Drugs, Tranquilizers, Vitamins and Antibiotics." The table showed for each of the principal drugs within these categories the share of production accounted for by each of 16 leading drug manufacturing companies. During the course of my presentation Dr. Smith presented certain statistics on concentration which he indicated were taken from an analysis prepared by the National Industrial Conference Board. That afternoon the PMA issued a press release taking issue with my presentation and stating that the table which I had offered was "grossly misleading." In this memorandum I wish to offer a few comments concerning the press release and Dr. Smith's testimony on this issue.

1. The press release states, "The Senator's staff has attempted to show with this chart that 16 companies controlled two-thirds of the 1958 dollar volume of prescription drug sales.

The PMA is in error. I made no statement of any kind concerning the degree of concentration in "prescription drug sales" or in any such general category. the figure "16" "two-thirds" were used in my presentation but in an entirely different context. They were employed to show the relative aggregate importance, in terms of the total value of all ethical drugs, of the individual drugs for which concentration ratios were individually shown in the table. The table presented concentration ratios individually for 51 products. These products, I pointed out, "represent at least two-thirds of the 1958 value of ethical drugs" (transcript, p. 3347). Apparently the PMA has arrived at its erroneous conclusion by substituting "16 companies" for "51" products in the sentence which ends "* * * represent at least two-thirds of the 1958 value * * *."

Having thus misstated my testimony the press release proceeds to contend that this level of concentration in "prescription drug sales" is lower than in other industries. Since the figure employed by the PMA is erroneous, the comparisons with other industries are meaningless.

2. The press release misstates the nature of the table by conveying the impression that what is presented is not the concentration of production of the drugs themselves but the concentration of "medicinal chemicals" which are employed as raw materials in the manufacture of drugs. The release states, "This chart shows, for example, that three firms produce all the bulk chemicals that go into a corticosteroid drug known as prednisolone." The table does not show the concentration of "bulk chemicals" that "go into" this or any other drug; it shows the concentration of production of prednisolone itself. All that is added to prednisolone before it is sold to the final customer is a very inexpensive inert material, which serves as a binder holding the product together when it is pressed into the form of a pill or tablet. There are bulk chemicals of this kind or another which do go into the various products shown on the table. Both of the oral diabetic drugs shown, Orinase and Diabenese, are manufactured from bulk

chemicals, isocyanates. The table does not show the concentration of production of isocyanates; it shows the concentration of production of Orinase and Diabenese.

3. The release implies that I ignored the fact that one product within a category, such as hormones, may compete with other products within that same category. It states, "Furthermore, the chart does not explain that prednisolone is a product that is itself competitive for prescription purposes with more than half a dozen corticosteroids." In my testimony I did note this fact and then went on to call attention to its limited significance:

"* * * while it is true as we have certainly developed and tried to stress in both the tranquilizer and the corticosteroid hearings that there is a certain degree of product competition between one product and another product, nonetheless there is also a certain degree, a very high degree of company specialization, the same companies appearing among the different products within a different broad product category. For example, of the 9 hormone products, only 7 of the 20 largest companies are represented. In diabetic drugs there are only five companies, in tranquilizers only six. In sulfas, there are only three. In vitamins there are only six, in antibiotics, other than penicillin, eight, and, in penicillin, seven.

"Now, whether a given product is or is not competitive with another product, such as dexamethasone, which is held to be superior by Merck to predisone, it is still a fact that the production of dexamethasone is concentrated entirely in the hands of Merck and Schering, and the production of prednisone is concentrated to the extent of 89 percent in the hands of Schering.

"This same pattern obtains throughout all of these product categories, with the exception of the older forms of penicillin."

Further examination reveals that, even after making full allowance for the possibilities of substituting one drug for another, the level of concentration is by any standard remarkably high. In steroid hormones, of the nine products shown on the table the total output is accounted for by one company in the case of three, by two companies in two, and by three companies in the remaining four. Dexamethasone, the largest selling product in this group with over 30 percent of the sales of all steroid hormones, is produced entirely by two companies, Merck and Schering, which with one other, Ciba, account for all of the sales. While it is true that the "predni" drugs are currently sold in bulk form to smaller companies, such sales, under contracts now in effect, will cease if the patent is awarded to any of the firms involved in the current interference proceedings, other than Syntex.

In diabetic drugs there are two principal producers of insulin—Lilly with 77 percent and the Squibb Division of Olin Mathieson with 19 percent. This is the concentration facing the majority of diabetic patients who cannot be transferred to the oral antidiabetic drugs. Those who can be placed on oral medication are virtually limited to two drugs, tolbutamide (Orinase) and Chlorpropamide (Diabénese).[1] A complete monopoly of sales of the former is held by Upjohn and of the latter by Pfizer.

Of the two types of tranquilizers, Smith Kline and French, with its Thorazine and Compazine, is dominant in the "potent" drugs, while Carter Products, with its meprobamate, has no close rival in the "mild" drugs. Smith Kline and French is the exclusive domestic licensee of Rhone-Poulenc, while Carter licenses only American Home Products. Perhaps because of competition with rauwolfia serpentina, of which it is a derivative, or a lack of confidence in the patent, reserpine is sold in bulk or licensed to small drug companies by Ciba.

All of the nine sulfa drugs shown on the table are manufactured by only three firms—the Lederle Division of American Cyanimid, Hoffmann-LaRoche, and Merck. In eight of the nine products one or the other of these companies has a complete monopoly. In the case of only one, sulfathiazole, are there as many as two producers—American Cyanimid with 73 percent and Merck with 27 percent.

Of the nine vitamins shown, three are produced exclusively by a single company (two by Merck, and one by Hoffmann-LaRoche), while in three others Merck together with Hoffmann-LaRoche produces 100 percent of one, 89 percent of another, and 95 percent of the third. In still another Merck shares the entire output with Hoffmann-LaRoche and Pfizer. And the latter two firms account for 64 percent of the output of the eighth product. Only in the case of one vitamin,

[1] As compared to the other two, sales of a third oral antidiabetic drug, DBI, produced and sold entirely by U.S. Vitamin, are quite small.

folic acid, are neither Merck nor Hoffmann-LaRoche among the principal producers, and here American Cyanamid produces 65 percent of the output.

Among the wide-range antibiotics shown, by far the most important is tetracycline followed by chloramphenicol. Tetracycline is produced entirely by three companies—American Cyanamid, Bristol Myers, and Pfizer, which together with Squibb and Upjohn (the only other sellers) have been proceeded against by the Federal Trade Commission on the grounds of having entered into a price-fixing conspiracy in the sale of this product. Parke, Davis has a complete monopoly in both the production and sale of chloramphenicol.

"This same pattern obtains throughout all of these product categories, with the exception of the older forms of penicillin."

4. During the testimony Dr. Smith sought to contradict my testimony by reading into the record excerpts from a report on concentration in the drug industry prepared for him by the National Industrial Conference Board. The findings of this report, as set forth by Dr. Smith, are in terms of the broad categories "drugs and medicine" or "pharmaceutical preparations." From the statistical data which he presents, it is clear that he is referring to the census industry, pharmaceutical preparations (SIC code 3284). Commenting on these findings I pointed out that of the bodies of universe data available for the drug industry, the Tariff Commission figures are preferable to those of the Census of Manufactures in that the product categories are more narrowly defined and thus more meaningful.

"There are two sources of what I refer to as universe totals or denominators of concentration ratios for drugs among the various government agencies. One is the U.S. Tariff Commission. The other is the Census of Manufactures. The Census of Manufactures, as we all know, obtains total shipments figures for all U.S. industries, and it has happened that, because of its necessary preoccupation with obtaining valid statistics for the entire economy, the product categories used for the drug industry in the Census of Manufactures are excessively broad for any meaningful purpose. It is for that reason that the Tariff Commission has, for years, been obtaining more detailed product data.

"I believe that the Tariff Commission data for drugs is much more widely utilized than are the Census of Manufactures figures."

At the time I had not realized just how excessively broad the census product and industry definitions for the drug industry actually are. Further analysis reveals that the census industry used Dr. Smith, pharmaceutical preparations, is almost entirely composed of six "5-digit" product classes, one of which accounted in 1954 (the year cited by Dr. Smith) for over half of the total of the industry's shipments. This turns out to be one of the "all other" or "not elsewhere classified" product classes of the census, specifically "All other pharmaceutical preparations for human use." In 1954 it accounted for $830,787,000, or 51 percent of the industry's total shipments of $1,643,140,000.

In studies of concentration the limited meaning of the "not elsewhere classified" product classes is well recognized. The customary practice is either to omit them entirely or to carefully call attention to their lack of significance. Thus in its report, "Changes in Concentration in Manufacturing," the Federal Trade Commission states:

"* * * it is a general rule that the broader and more heterogeneous the definition of an industry, the lower will be the concentration ratio. If an industry has only one or a few products, the concentration ratio for the industry will not be greatly dissimilar than the ratios for the individual products. But this would not be true in an industry of many products which are neither close substitutes for each other nor feasibly produced by the same facilities. In such industries, it is to be expected that different firms will tend to specialize in the production of the different products. Thus the level of concentration for each of the products might be quite high, but the share of the industry's total economic activity accounted for by any small group of firms (e.g., its four leading producers) would be relatively low. Outstanding illustrations of industries of this type are the so-called not elsewhere classified industries, an example of which is 'food preparations, not elsewhere classified'; this industry embraces establishments engaged in such diverse activities as roasting coffee, baking ice cream cones, manufacturing peanut butter, frying potato chips, preparing ready-to-mix desserts, etc."

When reference is made to the subject of this inquiry (and of the table criticized by Dr. Smith), namely ethical drugs, instead of the broader category of pharmaceutical preparations, the relative importance of this "all other"

product class becomes even greater. This is apparent from the following table which shows the value of shipments in 1954 for the six product classes which comprise more than 96 percent of the industry's total.

Industry and product class	Value of shipments	Percent
	Thousands	
28341: Pharmaceutical preparations for veterinary use	$85,777	5.3
28342: Antibiotic preparations for human use	252,897	15.5
28343: Cough and cold products	64,561	4.0
28344: Laxatives, cathartics, antiacids	122,377	7.5
28345: Vitamins for human use	214,512	13.1
28346: All other pharmaceutical preparations for human use	830,787	50.9
Pharmaceutical preparations (total)	1,643,140	100.0

The first product class, pharmaceutical preparations for veterinary use (28341) is clearly outside the field of ethical drugs, while three of the other classes embrace products sold principally as proprietary drugs; these are cough and cold products (28343), laxatives, cathartics, antiacids, etc. (28344) and vitamins for human use (28345). Thus substantially more than half of the shipments of ethical drugs is represented by shipments of just one product class, which include hormones, diabetic drugs, tranquilizers, sulfa drugs, antihistamines, narcotics and many others. The value of such a catchall category is virtually nonexistent for any purpose; it is particularly useless in rebutting findings based upon the meaningful, narrowly defined products of the Tariff Commission.

EXHIBIT 289

[From the Journal of the American Medical Association, Feb. 12, 1944]

COUNCIL ON PHARMACY AND CHEMISTRY

The Council has authorized publication of the following statement:

AUSTIN E. SMITH, M.D., *Secretary.*

THE COUNCIL ON PHARMACY AND CHEMISTRY

MEMBERSHIP, ACTIVITIES, METHOD OF OPERATION, ATTAINMENTS

(Austin E. Smith, M.D., Chicago)

During these days of proposed revision, increasing enforcements by administrative bodies and other restrictions which seem to be a sign of the times, it is refreshing to observe how a body with no legal power can create changes with far reaching effects. In the past 39 years there has been no single body which has created as much change in the practice of therapeutics as has the Council on Pharmacy and Chemistry. The council was organized in 1905 to serve the medical profession and the public by providing accurate information on the status of agents used in the treatment of disease. Since that time its activities have grown, and as it enters its 40th year in 1944 the members can look back with satisfaction on the service that has been provided. Even though the council is an integral part of the American medical profession, many members profess confusion regarding council makeup and activities. It is to dispel some of this confusion that this paper is offered.

MEMBERSHIP

The council consists of 17 outstanding scientists, each associated with some recognized medical center, and a secretary who is a full-time employee of the American Medical Association with an office in Chicago. The members are David P. Barr, professor of medicine, Cornell University Medical College; J. Howard Brown, associate professor of bacteriology, Johns Hopkins University School of Medicine; S. W. Clausen, professor of pediatrics, University of Rochester School of Medicine and Dentistry; Harold N. Cole, clinical professor of dermatology and syphilology, Western Reserve University School of Medicine;

Morris Fishbein, editor of the Journal of the American Medical Association; E. M. K. Geiling, professor of pharmacology, University of Chicago School of Medicine; Robert P. Herwick, chief, Drug Division, U.S. Food and Drug Administration; Chester S. Keefer, Wade professor of medicine, Boston University School of Medicine; Eugene M. Landis, professor of physiology, Harvard Medical School; James P. Leake, medical director, Epidemiological Section, National Institutes of Health; George W. McCoy, professor of preventive medicine and public health, Louisiana State University School of Medicine; Perrin H. Long, professor of preventive medicine, Johns Hopkins University School of Medicine; Stuart Mudd, professor of bacteriology, University of Pennsylvania School of Medicine; E. M. Nelson, chief, Vitamin Division, U.S. Food and Drug Administration; W. W. Palmer, Bard professor of medicine, Columbia University College of Physicians and Surgeons; Elmer L. Sevringhaus, professor of medicine, University of Wisconsin Medical School, and Torald Sollmann, professor of pharmacology and dean, Western Reserve University School of Medicine. Many others will be remembered for their long association with council activities and scientific contributions. Since the council's organization on February 11, 1905, there have been appointed 60 members. The average tenure of membership has been 11 years.

The members of the council serve without remuneration but freely give a large amount of their time and effort to the council's work. This work cannot be estimated purely in terms of hours per week, as every afternoon or evening sacrificed by a council member for consideration of some council problem means the loss of that time for some other urgent problem which may relate to his family or the institution with which he is connected.

The Council on Pharmacy and Chemistry has served as a model for the Council on Physical Therapy and the Council on Foods and Nutrition of the American Medical Association and for the Council on Dental Therapeutics of the American Dental Association. There is at the moment no successful counterpart outside the United States, although representatives from several countries recently have visited the council office to learn the details of council functioning so that similar bodies can be established in these other countries when the time seems propitious.

ACTIVITIES

In addition to considering proprietary drugs the council reiews the status of other agents which the medical profession, and even the public, may be urged to use, publishes reports on claimed advances in the use of medicinal preparations, with the Chemical Laboratory elaborates standards on drugs introduced into materia medica, provides information for physicians, members of the armed forces and others, sponsors the publication of several books and numerous research projects, and maintains a cooperative relationship with many governmental and nonofficial organizations. Its information and advice are frequently sought; it is often invited to participate in cooperative projects with other agencies. It does not hesitate to initiate an investigation when a grievous error occurs in the manufacturing and dispensing of drugs; a few such instances are well known to all. The council also maintains cooperative relationships with many countries other than the United States, and much correspondence is exchanged on problems of mutual interest.

The publications sponsored by the council include New and Nonofficial Remedies, Useful Drugs, Epitome of the U.S. Pharmacopeia and National Formulary, Annual Reprint of the Reports of the Council, and Glandular Physiology and Therapy. It also supervises the preparation of the Intern's Manual. By the end of 1943 well over 400,000 copies of council publications had been distributed over the last 20-year period. Of this number New and Nonofficial Remedies comprised about 260,000 copies.

The council has assumed ever increasing importance in the field of medicine until now it is truly considered one of the leading authorities on rational therapeutics. There are few who are not familiar with the council's seal, and yet there are many who have only the vaguest conception of how this seal is issued.

PROCEDURE FOR ACCEPTANCE

The use of the seal is restricted to those products which have been found acceptable for inclusion in New and Nonofficial Remedies, a yearly publication of the council. The council considers articles for listing in this book according to a set of rules which permit consistent and fair application for all firms and

their products. The rules essentially provide that an accurate statement of composition must be provided; suitable tests must be available for identification; the article cannot be advertised either directly or indirectly to the public unless it is one of those agents information on which the council feels may be made available to the public (for example, first aid measures, laxatives, vitamins); statements regarding origin and source of raw material must not be misleading; therapeutic claims shall not be exaggerated or misleading; the label must list the active substances; the name under which the product is sold shall not be misleading or suggestive of diseases or therapeutic indications; patent numbers and trademarks, if any, must be furnished, and the preparation must not be unscientific.

Obviously it is the right and duty of the physician to know the essential composition of the drugs he prescribes. He also wishes to know if the mixtures are unnecessarily complex, being mindful of the fallacy of prescribing unnecessary potent agents and prescribing routinely several drugs of different actions in fixed proportions in one preparation. The physician also is justified in demanding that the claims offered on behalf of a product which he is urged to use should be in line with demonstrable facts. The value of such rules is self evident. When the Council insists that manufacturers keep their advertising material within the limits prescribed by Council rules, it serves to protect the public and the physician.

Some manufacturers more interested in self gain than in the welfare of the public or the physician formerly used the doctor as a means of promoting their medicine to the public. The technic was simple: Promoters were convinced that the easiest way to establish a demand for their goods on the part of the public was to make available a catchy name, especially if it was suggestive of a disease or treatment, and advertising material which could be read by the curious patient and his friends and relatives. The late Dr. Simmons referred on more than one occasion to an article on proprietary medicines which was published in an advertising journal; this read in part "But the patent medicine of the future is the one that will be advertised only to doctors. Some of the most profitable remedies of the present time are of this class. They are called proprietary medicines The general public never hears of them through the daily press, for their publicity is secured through the medical press by means of the manufacturer's literature." This statement appeared in print almost forty years ago, and yet it is still admirably descriptive of some present day promotional practices.

PROPRIETARY NAMES

The profits to be made by a pharmaceutical house from the sale of a drug which is offered under an official name usually is quite moderate. The profits to be made from the sale of the same drug sold under a proprietary name is frequently enormous. For example, a survey in the September 1941 issue of a popular price list of drugs revealed that the total cost of an ounce of each of nineteen substances under a protective name was $48.67, whereas the total cost of an ounce of each of these substances under a nonprotected name was $15.67; thus, the cost of a proprietary name to the consumer would be $33. This represents retail price, the material being reduced to terms of ounces for convenience. Included in these nineteen agents were sedatives, vasaconstrictors, local anesthetics, anti-infective agents, and analgesics. Some years ago a large hospital in an eastern city adopted a set of specific regulations which, in effect, did away with the expense of prescribing proprietary agents when official counterparts were available, and unnecessarily complex mixtures and the absurd practice of prescribing names instead of therapeutically active agents. This pharmacy within one year effected a saving of $50,000. Thus the manufacturer frequently considers it of prime importance that his product be endowed with his own protective name.

With the desire of encouraging the introduction of drugs that are an advance over those previously known, the Council does not offer objection to the application of a proprietary, exclusive name, provided the drug to which it is applied really presents something new. Thus the Council recognizes such names for products not previously known, for substances previously known but not used in medicine, for unique and worth while variations for making this drug available, and when a known substance is found to have new value, even if that substance was used in the practice of therapeutics at an earlier date. Obviously the new value has to be worth while. If a manufacturer will read the Council rules, he will know if his new product merits recognition under a proprietary

name and if the chosen name is acceptable. However, he frequently spends several years promoting the agent without regard for the rules and then feels offended if the Council will not accept the agent under the proprietary name. How simple it would be if the manufacturer would place the name before the Council when the product is ready for the market (and even before it is ready for the market) and ask the Council to consider its acceptability in the event the product is submitted to the Council for inclusion in N.N.R. If any changes are necessary they can be made easily at the time of this preliminary consideration with no inconvenience or expense for the manufacturer. The present trend is to do this.

One of the greatest evils of the use of protected names lies in the confusion they create. The old story of methenamine being prescribed in one prescription under six different names is a standing joke in materia medica classes, and yet other examples just as questionable are evident in everyday practice. In the United States the practice among the better pharmaceutical drug manufacturers seems to be decreasing, partly because these organizations are acquiring critical medical and other technical personnel and partly because experience shows a certain amount of resentment on the part of the medical profession; there is a greater tendency to reserve proprietary and protected names for specialties of the house rather than for official agents. However, there is still room for much improvement.

It is interesting to observe the nomenclature situation in an allied country, England. There, sulfanilamide is offered under fifty odd names, including Antistrept, Astreptine, Bacterimide, Bactericide, Cepticide, Erysipitan, F1162, PABS, Septinal, Strepamide, Streptamide, Streptosal, and Therapol. Can any one hope to memorize fifty such names, none of them chemically descriptive, for one agent? Sulfapyridine is sold or prescribed under nine different names, sulfathiazole under seven. Even the Lancet, an English publication which must depend a great deal on advertising for financial security, presented an editorial in August 1943 entitled "Babel in the Drug Trade." This editorial reads, in part, "It is questionable whether the British drug trade in its present form makes the most of its great opportunities for public service. The war has revealed unexpected deficiencies * * * particularly disappointing is the attitude of parts of the trade towards the canons of ethical nomenclature * * * the Council on Pharmacy and Chemistry of the American Medical Association very rightly refuses to recognize proprietary names for articles which are included in their Pharmacopeia and National Formulary. In the marketing of original articles they say 'The legitimate interests of the producer are fully served by identifying such product by appending the name or initials of the manufacturer, or by use of a general brand mark.' The same must be true over here."

The Council has met many arguments in its consideration of the nomenclature problem. In some instances there were honest difference of opinion; in others arguments were motivated solely by commercial reasons. And yet, in spite of these arguments it is interesting to notice that the names which have been coined or adopter by the Council as nonproprietary names have come into popular use, are listed in the U.S.P. or are recognized by judicial bodies as the common name. Excellent examples are arsphenamine, procaine, cinchophen, viosterol, chinofon, menadione, sulfanilamide, sulfapyridine, sulfathiazole, riboflavin and thiamine hydrochloride.

Frequent representatives of manufacturers inform physicians that there product is not accepted "simply because of the name." As a result some physicians feel there is much unnecessary ado about nomenclature. Examination of the Council's past considerations (this is possible because every item of correspondence and other activities has been preserved and bound since 1905) refutes this unjust criticism and proves the fairness of the principles in the preceding paragraphs. In the past twenty years only eighteen articles have been rejected primarily because of the manufacturer's refusal to abandon a proprietary name which was in conflict with Council rules. Included were four tetraiodophenolphthalein sodium preparations, two bismuth suspensions, one barium sulfate suspension, one colorless tar prepartion and one liquid petrolatum.

REFEREE'S CONSIDERATION

Admission of an article to N.N.R. does not imply a recommendation or "approval." It merely means that no conflict with the rules has been found by the Council and that the product has merit as a therapeutic agent. All products are

submitted in accordance with certain rules. The firm must provide specimens of advertising material, specimens of the drug for laboratory examination, evidence in supoprt of the efficacy and proposed claims, information on trade name and synonyms, definition, preparation, properties, tests, pharmacologic action, therapeutic indications, toxicology, dose, how supplied, manufacturer, patents trademarks.

The Council office submit the firm's data, with other information in its files, to a Council member who serves as a referee. The referee prepares a report or puts in finished form a rough draft, which may have been prepared in the Council office by a consultant, and returns it to the Secretary, who, every two weeks, transmits such material to the other Council members by a mimeographed bulletin. Accompanying this report are specimens of advertising material and other pertinent material which may aid the Council members in their decisions. Thus, each Council member has an opportunity to judge for himself the usefulness of the product, whether it complies with the Council's rules, and the report offered by the referee, who, incidentally, is an authority in the field of the subject which he is asked to consider.

In the next issue of the Bulletin to Council members appears the discussion by all members which may elicit information not available to the Council office or the referee. In the following issue of the Bulletin appears the vote to accept the product, reject or hold in abeyance. A three-fourths affirmative vote of the voting members (a nonvoting member being one who may be ill, temporarily out of the country or otherwise occupied) is necessary for the acceptance or rejection of a product. If a product is accepted the firm is notified immediately of the outcome of the Council's consideration. If any advertising claims must be revised or deleted or more supporting evidence provided before the product stands finally accepted, the firm is so notified. On the removal of these conditions the product then becomes accepted and a description is submitted to the editor of THE JOURNAL for publication and subsequent transferral to New and Nonofficial Remedies. If insufficient evidence is submitted by the manufacturer to justify the acceptance of its product at the time of consideration, the manufacturer is notified so that he may submit the lacking information. If he refuses or is unable to do so the product may be held in abeyance for further investigation or be immediately rejected. The manufacturer always is given opportunity to argue the Council's decision and may at any time ask the Council to reconsider the status of a rejected product.

Occasionally there is brought to the attention of the Council a new product which shows promise of usefulness but on which the experimental work has not been sufficient to make it ready for general use by the medical profession. In order to assure proper and controlled clinical study of such a product the Council issues a preliminary report on identity and standards, on the experimental work that has been done and on the further study that may appear desirable.

With the execption of the continuance of acceptance of a drug, all the Council's actions, whether of acceptance, rejection, or omission, are published in THE JOURNAL and later in New and Nonofficial Remedies or in the Annual Reprint of the Reports of the Council on Pharmacy and Chemistry. This gives full publicity for all the Council's decisions to manufacturers and physicians alike.

The Council insists that the manufacturer must supply evidence for therapeutic and other claims. The Council is not equipped to initiate a clinical investgation of every drug that is submitted for its consideration. It does have the facilities of seventeen Council members to draw upon, the members' associates and other outstanding authorities throughout the entire country, these men serving gladly as Council consultants. A chemical laboratory maintained at AMA headquarters examines the chemical composition of every submitted product before it is admitted to New and Nonofficial Remedies. Sometimes a manufacturer offers inadequate evidence to the Council when his product is submitted. Needless to say, this question of submitting evidence has been the cause of much confusion in the past and undoubtedly the cause of some criticism of the Council by certain manufacturers. It is anticipated that from now on this difficulty will approach a minimum, because the outline by which each product is presented demands that the evidence must accompany the presentation. A scheme has been set up whereby well defined steps must be followed by the manufacturer when he presents his product so that all necessary data are available at one time for the Council's consideration. These steps are outlined in a booklet of rules which is available on request.

OFFICIAL DRUGS

Official agents and combinations of official agents are exempt from Council consideration if they are marketed with no unestablished claims and under the official name or synonym. Undoubtedly there are many who have noticed that N.N.R. contains official agents as well as nonofficial ones. This is because the Council feels that there are many official agents about which the medical profession is not sufficiently well informed, and since the U.S.P. does not provide statements of actions and uses the Council makes these available in N.N.R., Useful Drugs and the Epitome of the U.S.P. and N.F. Each year N.N.R. is revised so that the claims are in line with those generally accepted at the time of revision. Such yearly revision provides a book to which the physician may turn for authoritative and up-to-date information on the therapeutic value of drugs. Three years after acceptance each product is reviewed to determine if it is still in keeping with the Council's rules; if it is, the agent is accepted for another three years. At the end of each interval of three years, or more often, it is reexamined.

The agents described in the official compendiums (U.S.P. and N.F.) and New and Nonofficial Remedies total in number about 2,700. The U.S.P. lists approximately 650 articles, the National Formulary 730, and New and Nonofficial Remedies describes 1,300 agents. Without an actual count of the index cards which have been kept since the Council's inception in 1905 it has been estimated that the Council has probably considered from 250 to 400 products every year, thus providing an examination and evaluation of about 15,000 products in the last thirty-nine years. In addition, it has given consideration, not with the view to acceptance or rejection but for the purpose of making status reports, to probably 2,000 or more articles. U.S.P. XII and First Supplement will include about 114 agents previously described in N.N.R. and for which the Council had already provided standards. The articles, described in the two official compendiums U.S.P. and N.F. and in N.N.R. provide an array of useful agents from which any medical practitioner may prescribe, regardless of his specialty. These books include almost all the useful drugs which are on the market; certainly they list all known agents which are essential to the practice of medicine. Of course, new drugs are developed, and as they are developed the Council watches closely their progress. When a firm submits a new one it is given immediate consideration by the Council. Sometimes the firm does not submit a product for various reasons, in which case the Council may initiate a report so that proper information may be available for the medical profession.

MISREPRESENTATIONS BY "UNACCEPTED FIRMS"

Some may wonder why certain firms do not stand "accepted" by the Council. Some of these firms have no products accepted simply because they have not asked for Council consideration. Others do not have accepted products because their policies have not yet been brought into conformance with Council requirements. However, a number of new firms were included in N.N.R. in the past two years, and several more will probably be listed within the next few months. All these firms have taken it upon themselves to change their line of products and advertising policies. Old outmoded mixtures are being discarded for new, truly effective agents. Misleading and therapeutically sugggestive names are being replaced by official or descriptive names. Advertising policies are becoming more conservative so that the physician can feel reasonably certain that the promoted claims are within reasonable bounds of accuracy. At present there are about 150 firms with products accepted by the Council.

Representatives of a few firms whose method of doing business has not resulted in recognition by the Council have in some instances made untrue representations to the effect that the Council charges a fee for examining drugs or that it "costs too much" to get a product passed by the Council, or that it is necessary to take out so much advertising in THE JOURNAL before the Council will accept a product. Such statements are completely false. The Council has never accepted, or permitted to be accepted, a cent of remuneration in any form for the consideration of products. The cost of the Council on Pharmacy and Chemistry, as well as that of the other AMA councils, is borne entirely by appropriations made by the Board of Trustees of the American Medical Association. The Council is not influenced in the slightest by any proffer of advertising patronage; Council members are not advised by the Secretary of any information with respect to a proffer of advertising and there is no possibility of their action being influenced by where a product is advertised. If the Secretary learns of such a proffer,

the firm is notified that it will have no effect on the Council's consideration. If any such charges against the Council reach the members of the profession, they should demand immediately that such charges be either substantiated or retracted.

DRUGS SOLD TO THE PUBLIC

Sometimes the Council is asked why it does not consider for acceptance more agents sold to the public. In the first place, such an undertaking would be a tremendous one. No one body of moderate size could ever hope to give consideration to all the agents that come and go. Of greater importance is the status of claims offered to the public; are such agents sufficiently effective to meet all the claims advanced? If they are this effective are they the kind of preparations that should be in the hands of medically untrained individuals? The evils of self-diagnosis and self-treatment are self-evident.

ACCEPTABILITY OF COUNCIL RULES

Considering that the Council has no legal power, its power being only that derived from the press, enthusiastic followers and use of the seal, manufacturers on the whole are fairly good Council supporters. This has been evident even from the beginning, when the Council first adopted a set of rules and sent them to the manufacturers for comment. Most of the replies were favorable, some even enthusiastic—an indication that the aims of the Council were essentially similar to those of the higher class of pharmaceutical manufacturers. A few were openly antagonistic, but this antagonism bore almost a direct correlation with the practices of the firm. Torald Sollmann said in 1908 "The Council is bound to conflict with the commercial element where this element conflicts with scientific progress; the manufacturers on the other hand must keep an eye on the dividends. * * *" It is interesting to note that the rules adopted by the Council in 1905 are essentially those in operation today, the only differences being editorial improvements and minor changes and additions which have been necessary from time to time to clarify the rules. After these rules had been in operation for half a year the Council arranged for a conference with the representatives of large manufacturing houses for an open discussion. This should be an answer to those who may ask if the Council's rules are sufficiently lenient. Apparently the manufacturers were satisfied at that time with the rules, and certainly consistent application over thirty-eight years has resulted in fairness for all. The Council has been and still is ready to consider carefully any suggestions for the improvement of these rules or of any activity in which the Council may be engaged.

DELAY IN COUNCIL ACTION

Occasionally the Council is criticized on the ground that it takes too long in its deliberations. This criticism deserves comment: Prolonged delays are almost invariably due to failure on the part of a manufacturer to submit the things for which he assumes full responsibility, for example, evidence or revised advertising claims. A product which is submitted with all necessary information and which does not violate the Council's rules can be accepted within a period of from 6 to 10 weeks—surely not a very serious delay. If necessary, as when a manufacturer wishes his product Council accepted prior to bidding in certain contracts, or when a hospital or other body is anxious to have an immediate report, the Council can, by means of special Bulletins, complete consideration within 2 or 3 weeks. However, this is not a procedure that can be followed frequently, as it would upset the routine which has been found most effective to dispose of Council considerations.

Occasionally short delays are created by the referee being pressed at the moment with other duties. But as soon as these are removed the referee turns immediately to the Council problem. If he desires to prove or disprove certain claims by actual trial in his laboratory or clinic, a further short delay may result; but obviously such experimentation is of benefit to the physician and even the manufacturer submitting the questioned claims. The Council members assume a grave responsibility in declaring a product acceptable or nonacceptable, and they demand that the necessary data for careful consideration be available.

Sometimes manufacturers who have not had experience with the Council fail to understand what constitutes adequate evidence. The kind of evidence which the Council wants is that which will stand up before any critical examining body, the kind which a scientist would not be ashamed to present before

a medical or other scientific group. Signed statements, even when they come from the best of men, do not constitute evidence if they are merely testimonial in character; several hundred signed testimonials are not equal to one or two good pieces of research.

OTHER QUESTIONS

Some critics have averred that the average physician is capable of judging the value of a product. Unquestionably he is trained to observe clinical responses. But has he the time and the necessary detailed knowledge of bacteriology, pharmacology, toxicology, endocrinology, and other special branches of medicine always to determine which patients might have recovered without drug intervention, which preparations are unnecessarily complex, which contain agents that are incompatible, which may have lost part of their effectiveness because of partial absorption into the container or by oxidation and the host of other factors that must be considered? Many of the manufacturers with products accepted by the Council would be the first to say no. Each member of the Council has spent many years of special study in some particular field and is able to give more accurately and more quickly answers to questions concerning Council submitted products.

The Council occasionally is asked if there is need for its existence with the new food and drug legislation. The answer is "yes." In the consideration of a new drug application the Food and Drug Administration under the terms of the 1938 Federal Food, Drug, and Cosmetic Act is permitted to examine solely from the standpoint of safety. If this body attempts to question certain claims in the proposed advertising material it may be reminded by the manufacturer that advertising material not accompanying the market package is outside the jurisdiction of the Food and Drug Administration. Any action based on the consideration of claims for usefulness must be initiated on interstate shipments after a new drug application has been made effective.

Several considerations render it impossible for the Food and Drug Administration to consider the labeling and to determine the composition of all types of drug products after they have appeared on the market: first, limitations of the facilities and personnel made available for the enforcement of the Food, Drug and Cosmetic Act; second, the attention the Food and Drug Administration must give to the small segment of the industry that will always be engaged in the manufacture of products with wholly fraudulent or even vicious claims, and, third, the large number of pharmaceutical manufacturers and the tremendous number of products marketed. Furthermore, the Food, Drug, and Cosmetic Act is applicable only to products in interstate commerce and many products do not go beyond the borders of the State in which they are manufactured. Unfortunately altogether too many State enforcement agencies have inadequate facilities for control of these products. Under these circumstances for a considerable volume of therapeutic agents which the physician uses, the only definite assurance he has that the labeling claims for them are in accordance with sound medical opinion is the appearance on the package of the seal of the Council on Pharmacy and Chemistry.

The Federal Trade Commission cannot exert the necessary control over medical advertising directed to the physician, as the act under which it operates for all practical purposes exempts the drugs so advertised. The Post Office Department acts only on complaints and then reserves its action for schemes in which the mails are used for fraudulent purposes. Usually, articles mailed to the public are involved. The National Institute of Health is concerned only with serums, vaccines, toxoids and analogous products in which are included certain antisyphilitic preparations. Other agencies, judicial and nonjudicial, are concerned mostly with protecting the public.

What other organization, then, is there to aid the medical profession in its consideration of drugs which it is importuned to use? And what agency can move as fearlessly as the Council on Pharmacy and Chemistry and obtain such immediate, militant and effective support as can be provided by THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION and the state medical journals?

According to some of the letters reaching the Council ofice, it appears that many physicians believe a nonacceptable product to be satisfactory simply because the Council has not issued a report of rejection. The Council has made no attempt to report on all unacceptable products, but it can and is prepared to issue very many more reports of rejection if necessary. It wishes to avoid such action if possible, as the more logical approach to the problem

in which cooperation is desired and needed is to point the "do's" rather than the "don'ts." All of us are dealing with human individuals, few of whom like to be pushed, while many desire to be led.

ATTAINMENTS

The proprietary medicine business is essentially a development of the last seventy years. Nostrums placed on the market in the seventies and patented German synthetics became enormous in number in the early part of this century. Profits were immense and enticing. While a few of the compounds were of distinct value, the vast majority were simple mixtures of well known drugs put out under fanciful copyrighted names and for the most part fraudulent in one way or another; many were actually dangerous. Some were products from well known drug houses; the majority were put out by men who knew nothing of drugs or their effects but who went into the business of manufacturing medicines as they would any other business. Few hired competent chemical or medical advice, and as a result no statement was too silly or claim too extravagant. Those with a critical eye should have seen through the flimsy material offered as "evidence," but by persistent and occasionally clever advertising many were duped into buying and using these mixtures. Truly in these earlier days medicine in some instances could have been defined by the disappointed patient and physician as "the act or science of amusing a sick man with frivolous speculations about his disorders, and of tempering ingeniously until nature either kills or cures him." As early as 1879 the Association adopted resolutions condemning the use of these secret and semisecret mixtures, but it remained for the Council on Pharmacy and Chemistry to ferret out the acceptable and unacceptable agents for the physician and journal advertising pages. The job was a tremendous one and encountered much opposition in the early days. However, by earnest and altruistic effort the Council members brought about a semblance of order in the existing chaos.

Many of the original objectives of the Council have been firmly established, partly because of the increasing appreciation of its work by the medical profession, partly because of the position it holds as a consultant body, partly because of the more conservative and scientific attitude of the average drug manufacturer. As a result the commercial production and distribution of medicinal products is on a higher plane in the United States than in any other country. But there is still a long way to go; there must be close cooperation by all branches and representatives of the profession. If the advertising pages of medical journals are closed to medicinal agents which are not official or listed in N.N.R. there will be a powerful incentive for manufacturers to reach much more quickly the Council's objectives, which are those of rational therapeutics. "Pharmaceutical manufacture is largely a business; and as such it will be ready to defer to the demands of its customers—the medical profession." To be completely effective, such a program must be participated in by every one interested in progressive medicine, not by just a few others who may be part time participants according to their momentary interest. Otherwise the Council's efforts are stultified; representatives of the medical profession should be the Council's strongest supporters.

An interesting observation is the degree to which the public has become Council conscious. The Council office not infrequently has inquiries from physicians asking if a product is Council accepted simply because their patients have made such inquiries. Many people in lay audiences that are addressed by members of the headquarters staff ask about Council acceptance in a manner that indicates considerable familiarity with the Council and its seal. Any physician who fails to observe Council acceptance when he prescribes drugs for these persons is placed in an embarrassing position.

COOPERATION

A letter from the editor of a medical journal which was published in THE JOURNAL in 1913 reads, in part, "I do not believe that you realize just what the conditions are in the smaller communities * * * the question of supporting the Council on Pharmacy and Chemistry is * * * one which merits more consideration than we have given it. I do not believe that we are justified in making such strenuous efforts to reform the daily press and protect the public until after we have cleaned up our medical journals and made an effort to protect the public

from the evils of incompetency and dishonesty. * * * So far as I am personally concerned I am through with temporizing, and the 'kid glove' manner of handling the vital subjects. I propose to hit the nail on the head when I know that I am right. It is a little hard for the average editor to look over the advertising income and do the right thing at the expense of the purse, but I think the medical profession should be given to understand that such effort is to be supported or else the medical profession should cease to own and operate medical journals."

If the various representatives of medical and other scientific groups are prepared to support the Council's efforts, they can provide much aid. Many hospitals purchase only official and N.N.R. drugs. Many medical journals accept for advertising only official and N.N.R. drugs. Many teaching centers suggest only these agents with the exception of others offering much experimental promise. The Council's work can be brought to the attention of those apart from teaching centers and modern hospitals by appropriate journal editorials and other articles, which must be repeated frequently to be most effective, by discussions on the Council and other A.M.A. bodies at medical meetings, by reproduction in medical journals and elsewhere of Council pronouncements and by restriction of advertising of drugs in medical journals to official and N. N. R. drugs.

The members of the medical profession desire truthful information on drugs in which they may be interested. This is evident in the letters arriving at the Council office. To determine the source of this interest the letters arriving since the first of 1943 have been examined for point of origin. This examination failed to reveal any direct correlation between free distribution of N.N.R. to medical students and inquiries (which might be expected, as probably not more than 50 per cent of students remain in the state in which they graduate) or between number of physicians in each state and the number of inquiries from that state. The number of inquiries from the seven states with the least number of physicians was found to be 1 inquiry per 1,200 physicians over any given period; in the seven states with the greatest number of physicians the inquiries totaled 1 per 400 physicians—a threefold increase. Perhaps this enormous increase bears a fairly direct relation to the amount of educational activities carried on within the state.

The degree of education regarding Council functions lies entirely in the hands of those who are interested sufficiently to further this education; there seem to be increasingly receptive audiences—there is definitely an increasing interest by the majority of scientific bodies. This interest occurs not without reason and should be fostered by every one anxious to achieve the utmost in rational therapeutics.

EXHIBIT 290

[From Drug Research and Development, edited by Smith and Herrick, 1948]

CHAPTER 16—COUNCIL ACCEPTANCE

(By Austin Smith)

Pages 424, 425

As drugs accumulate complexity of identity and action, moreover, reliance on the chemical, pharmacologic, and toxicological experience and knowledge of the council's members has become almost imperative; no one physician, however extensively trained, is qualified to pass on the efficacy and safety of all of the drugs he is today being asked to employ in his practice.

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* * * the activities of the council are critical in nature; as an evaluating body, its recommendations would lose their force were they issued perfunctorily for every drug submitted or to every manufacturer.

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Nevertheless, this should prove no real obstacle in the case of an honestly promoted product. Somewhat similar data, as a matter of fact, are required in a new drug application under the Federal Food, Drug, and Cosmetic Act, and have not shown themselves to be overdifficult to furnish. Certainly, moreover, it is not unreasonable to ask that a drug manufacturer, producing and distributing a pharmaceutical to doctors, adequately justify his therapeutic claims and similarly establish his competency to manufacture it.

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The restrictions formerly placed on the use of protective names, which discouraged a number of applications, have now been raised to meet modern commercial practices. The fear that the council in giving publicity to a rejection of the application, may work considerable harm to the prestige of the manufacturer, is no longer completely warranted; for example, articles of questionable eligibility may now have their status determined before a formal presentation.

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Particular attention should be given to claims for nontoxicity. These are admitted only when they do not conflict with known facts. The council has cautioned physicians that a claim of lack of toxicity means only that toxic effects have not as yet been recognized with the doses that have been studied. Frequently, such apparently justified conclusions are ultimately reversed by extended experience. The same reservation applies to statements that a particular drug is nonirritating.

Applicant is required to submit objective data with sufficient citation of authority to enable the council to confirm the facts and establish the scientific value of the conclusions.

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Clinical evidence should be furnished in sufficient detail to permit an appraisal of the care with which it has been gathered and the legitimacy of its conclusions. Obviously, comparative trials facilitate and, indeed are frequently essential in reaching a judgment on this score.

Moreover, new advertising must be submitted for council examination on preparation and before its use. However, material merely reprinted from that previously accepted by the council need not be so reviewed unless it presents new claims; in the latter instance it should be accompanied by supporting evidence for council consideration before release. Since claims find reflection largely in such advertising, failure to comply with this requirement may act as sufficient ground for a rejection of the article.

Finally, references to medical literature in the advertising of an accepted product are required to include not only the name of the investigator but also the year of publication, although a full citation of the publication is permissible and preferred. Nor may the personal signature of a physician be used on the label or in the advertising of a product; this implies personal supervision and tends to create a misleading impression of therapeutic value, as, for example, that it is individually and specifically prepared for the user or his patient.

Protected names: The exigencies of pharmaceutical manufacture and intelligent prescribing are resolved in the rule that trademark names for medical articles are acceptable only if the council considers their use not to be harmful to health, and if the common or generic names are not unduly subordinated to such trademarks in the labeling and advertising of the product.

So far as trademark or "protected" names are concerned, the council is of the opinion that medical practice is best promoted by the use of a generic name for each drug, and not by the use of a different "protected" name for each brand of the drug. If nothing else, this avoids any needless tax on memory and the possibility of confusion and error. Nevertheless, it recognizes that the developer of a new remedy is entitled to designate it by a restricted name if only to protect his investment and expense. Consequently the council will accept a protected name from the discoverer of a drug or the firm first introducing it. Experience has shown, however, that any restriction to one protected name tends to prolong a monopoly unduly and moreover, prevents council acceptance of competing brands which, except that they employ other protected names, would ordinarily be acceptable. Accordingly, it will now accept several trademark names for the same article provided the article is not official, in which case the names must have been in use before the drug became official.

The common or generic name of the product must also be given on the labeling and in the advertising and cannot be unreasonably subordinated to the protected name. In cases of this nature, the accepted drug may be identified by adding the generic or official title to the protected one, as, for example, "Luminal, Brand of Phenobarbital," and "Benbedring, Brand of Amphetamine."

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An original combination marking a distinct improvement over available preparations may be so characterized, but it is rare that pharmaceutic prepara-

tions involve sufficient novelty warranting such action. The council is inclined to weigh any decision in this connection against its preference that mixtures should be so named, if possible, as to remind the doctor of the potent ingredients, and that mixtures are usually best described when the ingredients are adjusted to meet the individual case.

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Similar difficulties are apt to be encountered where a brief coined name is concocted for a product in its original form; for example, an elixir of a new hypnotic described as simply "Aliphal." Should the manufacturer subsequently decide to distribute the substance in powder form also, an entirely new name would become necessary, thus causing confusion to physicians and the trade. Consequently, the council holds that coined names for such substances are admissible only if they also describe the type or dosage form of the preparation, such as "Elixir of Aliphal," or "Aliphal Powder"—not "Aliphal" without qualification.

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Dosage: Wherever possible, the dosage and method of administration recommended in the current "New and Nonofficial Remedies" should be given. When the product is a new dosage form of an accepted article, or is one not previously recognized by the council, a detailed statement of the dosage and administration for the drug must be furnished, including mention of any necessary precautions peculiar to its mode of application.

How supplied: All dosage forms, sizes, and package forms of the article intended for council consideration should be listed at this point. It is necessary to state also whether or not the active ingredient is marketed in bulk.

Manufacturer: Not only the name of the firm responsible for the labeled finished product must be given but also the names of the manufacturers of all ingredients contained in the article.

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Patents and trademarks: If the drug is patented, the U.S. patent number should be furnished; if imported, the number of the patent in the country of its origin is necessary. Similarly, if the article bears a registered trademark, its number is required.

In the case of foreign registrations, the name or names under which it is registered should be given.

EXHIBIT 291

POINTS OF PROCEDURE FOR GUIDANCE IN ETHICAL DRUG PROMOTION

The Medical Section of the American Drug Manufacturers Association is firmly of the opinion that:

We individually and collectively should do everything possible to maintain the highest standards in our activities relating to the development and promotion of pharmaceutical, chemical, biological, and other medicinal products.

Since the medical profession is directly charged with the responsibility of providing the highest possible type of medical care to the American public and

Because the medical profession is best enabled to discharge its obligations to the public if prompt, complete, conservative, and accurate information concerning therapeutic agents is available to it, and

Because the public has a right to prompt, general, conservative, and accurate information concerning such agents after proof of their value in clinical practice has been established,

We believe that:

1. Any statement in promotional literature should be supportable by acceptable scientific evidence.

2. Quotations from the medical literature or from the personal communications of investigators or the paraphrasing of such quotations should not change nor distort the true meaning of the author.

3. If it is necessary to include comparisons of drugs in promotional literature, such comparisons should be constructive and made on a sound professional basis.

4. The release to the lay public of information relative to the clinical use of a new drug or to a new use for an established drug prior to adequate clinical

acceptance and public presentation to the medical profession of such a drug or use is considered not to be in the best interests of the American public or of the medical profession.

5. The use of trade names of prescription drugs in lay advertising is considered not to be in the best interests of the American public.

6. The appearance of physicians or of actors purporting to be physicians in television or radio advertising or in promotional literature intended for lay attention is considered not to be in the best interests of the American public.

7. The use of statements by a physician or of statements which purport to have been made by a physician in advertising intended for lay attention is considered not to be in the best interests of the American public.

8. Since the development of a new drug is recognized to be the result of the efforts of a scientific team rather than of any one individual, the use of individual names in releases for lay attention should occur rarely.

9. A trademark is private property and can be used legally in promotional literature only with the consent of the owner of the mark.

10. The medical department or the medical consultants of a pharmaceutical firm should review all medical claims and assertions contained in promotional literature prior to their release.

EXHIBIT 292

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

STATEMENT OF PRINCIPLES OF ETHICAL DRUG PROMOTION

(Passed by PMA board of directors on May 24, 1958)

We, members of the Pharmaceutical Manufacturers Association, recognizing our responsibilities and obligations to promote the public welfare and to maintain honorable, fair, and friendly relations with the medical profession, with associated sciences, and with the public, do pledge ourselves to the following statement of principles:

1. Prompt, complete, conservative, and accurate information concerning therapeutic agents shall be made available to the medical profession.

2. Any statement involved in product promotional communications must be supported by adequate and acceptable scientific evidence. Claims must not be stronger than such evidence warrants. Every effort must be made to avoid ambiguity and implied endorsements. Whenever market, statistical, or background information or references to unpublished literature or observations are used in promotional literature, the source must be available to the physician upon request.

3. Quotations from the medical literature or from the personal communications of clinical investigators in promotional communications must not change or distort the true meaning of the author.

4. If it is necessary to include comparisons of drugs in promotional communications, such comparisons must be used only when they are constructive to the physician and made on a sound professional and factual basis. Trademarks are private property that can be used legally only by or with the consent of owners of trademarks.

5. The release to the lay public of information on the clinical use of a new drug or to a new use of an established drug prior to adequate clinical acceptance and presentation to the medical profession is not in the best interests of the medical profession or the layman.

6. All medical claims and assertions contained in promotional communications should have medical review prior to their release.

7. Any violation of these principles brought to the attention of the president of the Pharmaceutical Manufacturers Association shall be referred by him to the board of directors.

EXHIBIT 293

JULY 31, 1959.

DR. J. O'NEIL CLOSS,
Executive Vice President,
Pharmaceutical Manufacturers Association,
New York, N.Y.

DEAR DR. CLOSS: Only a portion of my reasons for the extraordinary act of summary resignation are recounted in the enclosed copy of my letter of severance from employment as medical director of J. B. Roerig & Co. Division, Chas. Pfizer & Co., Inc.

The May 24, 1959, PMA "Statement of Principles of Ethical Drug Promotion" indicates that your president will bring to the attention of the PMA board of directors ethical code violations that come to his notice. Since I know you personally, I am writing to you directly to ask you to serve as an avenue to him. At the same time I am sending a copy of this letter to other acquaintances within the board.

The Sigmamycin complaint is already a matter of record. The Enarax inquiries are probably also known to you, although the background may not be. The failure to obtain clearance from any physician on Pfizer's staff for the TAO advertisements resulted in the rejection of the proposed material by several journals although "mailers" were sent out.

My respect for the pharmaceutical industry is not shaken. Indeed, I am to resume working in this industry in just 2 weeks. There is no rancor in my act. It is rather my fond hope that by policing its ranks the industry may help Pfizer to gain the perspective it lacks owing to its immaturity.

I submit that the medical profession and society in general expect and require of their great ally, the pharmaceutical industry, conduct that is in every way exemplary. Likewise, it is felt that the physician members of the industry must maintain an environment that is free of legal, ethical, and moral stigma.

Respectfully,

M. A. SEIDELL, M.D.,
Medical Director, J. B. Roerig & Co., Inc., Chas., Pfizer & Co., Inc.

EXHIBIT 295

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., January 29, 1959.

To the President and to the Official Correspondent:

The board of directors has instructed me to write each company president urging an immediate and, in the future, periodic review of the PMA "Statement of Principles of Ethical Drug Promotion." For your convenience I am attaching a copy of the statement. I invite your particular attention to the seventh principle which reads:

"Any violation of these principles brought to the attention of the president of the Pharmaceutical Manufacturers Association shall be referred by him to the board of directors."

As a result of this stipulation several alleged violations were called to my attention and in turn presented to the board at its meeting on January 8, 1959. There was a healthy and forthright discussion of the reported violations and others on which no formal complaint had been made.

Everyone agreed that violations of the statement of principles cast an undesirable and dangerous reflection upon the industry as a whole. Such violations provide opportunity for attack by our critics and have impaired the confidence of the profession and of the public. Failure fully to observe the spirit as well as the text of the statement of principles results in particularly harsh impact on the individual company involved.

The consensus of the board was that violations, since the adoption of the statement of principles, were generally without the knowledge and approval of the company presidents involved. Instead, it was the belief that the violations were due to a failure to control sales and promotional executives and advertising agencies who may not have regarded the statement with the seriousness that it deserves.

I am, therefore, directed to ask each company president to inform his organization and his advertising agency that the statement of principles must be rigidly observed. There seems to be no question that this will result in more effective promotion of each company's products and protection against costly, even devastating, loss of professional prestige with consequent damage to the company's sales volume. The alertness of critics to extravagant claims, to understatement of contraindications and other questionable practices makes it important for all of us to see that our sales and promotion executives and our advertising agencies understand their responsibilities in this situation.

The statement of principles clearly spells out the broad, and to some extent the specific, objectives of the PMA in respect to the promotion of ethical pharmaceuticals. We are, however, studying the practicability of identifying particular types of violations for the guidance of member firms. This project is now being explored and will receive further consideration at the next meeting of the PMA board. Any suggestions that you have will be most welcome.

In the meanwhile may I ask that you review the statement of principles with your executives and your advertising agency and reemphasize the need for their strict conformance. To facilitate this procedure we are enclosing extra copies of the statement.

GEORGE F. SMITH, *President.*

EXHIBIT 297

SEPTEMBER 18, 1959.

Mr. JOHN E. MCKEEN,
President, Chas, Pfizer & Co., Inc.
Brooklyn, N.Y.

DEAR JOHN: Several individuals have asked me about the challenge offered in Lear's latest article in the Saturday Review of Literature when he refers to referral of the subject which he discussed to the board of directors of the PMA. I have informed these inquirers that the subject will be on the agenda for the forthcoming meeting of the board. In view of this, is there any information that you would care to have me circulate to the board members prior to the meeting? If so, I would like to suggest that I receive this within the next day or so in order that it may be received by the board members before they leave for the meeting. Otherwise it would have to be presented to the members when they arrive in Washington.

Sincerely,

AUSTIN SMITH, M.D.

EXHIBIT 298

EXTRACT FROM MINUTES OF PMA BOARD OF DIRECTORS MEETING SEPTEMBER 30, 1959

John E. McKeen, on behalf of Chas. Pfizer & Co., Inc., submitted a detailed and documented reply to the charges made in an article entitled "The Case of the Substituted Drug," in the September 5, 1959 issue of Saturday Review that Pfizer had violated articles 2 and 6 of the PMA statement of principles of ethical drug promotion in respect of the promotional material distributed on its product Enarax. Mr. McKeen specifically denied that his company had violated any of the principles.

In view of the fact that the Federal Trade Commission is presently conducting an investigation into representations inserted in advertising media on behalf of the product Enarax which is marketed by the J. B. Roerig Co. Division (letter of June 4, 1959, from FTC to Pfizer), and Pfizer has submitted a response and is continuing to respond to the FTC in this regard, it is the consensus of this board that consideration of the charge of violations of the statement of principles is inappropriate, at least until the findings of the FTC are available.

EXHIBIT 299

EXTRACT FROM MINUTES OF FEBRUARY 8, 1960, MEETING OF BOARD OF DIRECTORS OF PMA

REPORT OF COMMITTEE ON PRINCIPLES OF ETHICAL DRUG PROMOTION

Mr. H. J. Loynd, reporting for Mr. George R. Cain, read the attached report. General approval was expressed of the report, and the proper officers of the association were authorized and directed to put its recommendations into effect.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION—STATEMENT OF PRINCIPLES OF ETHICAL DRUG PROMOTION

(Passed by PMA board of directors on May 24, 1958)

REPORT OF SPECIAL COMMITTEE TO REVIEW

This committee met in New York City, January 8, 1960, and reviewed not only the substance of the statement of principles of ethical drug promotion passed by the PMA board of directors on May 24, 1958, but also proper means for the implementation and enforcement thereof.

It was the concensus that while one or more sections of the statement might be strengthened or redrafted so as to eliminate more than one interpretation, the statement should be permitted to stand without change. The purpose of PMA and its several member firms in issuing and maintaining the statement remains the same; i.e., PMA and its several member firms have responsibility and obligation to promote the public welfare and to maintain honorable, fair, and friendly relations with the medical profession, with associated sciences, and with the public, in every proper and lawful manner. If any change were made in the statement at this time, improper implications might emanate therefrom in the trade press and in the minds of the several professions with whom we deal.

The committee submits to the PMA board of directors the following specific recommendations:

1. The board should reaffirm its original purposes in adopting this statement, and its policy that neither PMA nor any member firm shall maintain any interpretation or make any use thereof that shall be improper or unlawful.

2. Each violation of the principles as set forth in the statement and brought to the attention of the president of PMA shall be first referred by him to an ad hoc committee to be chosen by the chairman of the board. If the chairman has a complaint, then the members of the committee shall be chosen by the president. The committee shall consist of at least two members of the PMA board of directors who do not manufacture or distribute the same or a substantially similar pharmaceutical product to that in question, together with one or more additional members to be chosen from PMA sections if, in the opinion of the chairman or president, as the case may be, their professional talents may be of assistance. The general counsel of the association shall act as secretary of each such committee and report the findings thereof to the president who in turn will refer same to the board of directors. The respondent in each case shall, if he so desires, be given an adequate opportunity to appear both before the committee and the board of directors to make such response to the charge of violation as he may determine. Each such committee report shall be digested with the elimination of names and be available for the future guidance of the board of directors and member firms of the association in interpreting the statement of principles of ethical drug promotion. In pursuance of the stated policy of the association, it is specifically understood that no proceedings before, nor report of any such committee nor succeeding consideration by the board of directors should contain any matters which could result in PMA or any member firm maintaining an interpretation or making any use of the statement that would be improper or unlawful.

GEORGE R. CAIN, *Chairman.*

EXHIBIT 300

[From the Journal of the American Medical Association, Dec. 9, 1944]

COUNCIL ON PHARMACY AND CHEMISTRY

REPORT OF THE COUNCIL

The council has authorized publication of the following report. The outline in this report is offered as an objective: a pattern and not a regulation. However, it has been adopted for publication with the belief that it will be of help to manufacturers and scientists who undertake the investigation of new drugs.

AUSTIN SMITH, M.D., *Secretary.*

LABORATORY AND CLINICAL APPRAISALS OF NEW DRUGS

Walton Van Winkle, Jr., M.D., Robert P. Herwick, Ph. D., M.D., Herbert O. Calvery, Ph. D., members of the Food and Drug Administration, Federal Security Agency, Washington, D.C.; and Austin Smith, M.D., secretary of the Council on Pharmacy and Chemistry, Chicago [1]

A new drug should pass through several phases of investigation before it is declared suitable for distribution in commerce. It should be studied in the laboratory and in the clinic, the details of the study depending on the nature of the ingredients and the intended uses, but all investigations should follow a general plan which will permit a thorough understanding of the usefulness and toxic properties of the drug.

In considering new drug applications in the enforcement of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration is concerned primarily with evidence of safety. The Council on Pharmacy and Chemistry is concerned not only with the evidence of safety but also the evidence adduced to support the claims made for new drugs. Too frequently this evidence is found inadequate and the sponsors of new preparations, if they wish to provide the missing data, may find it necessary to repeat some of the more time-consuming and expensive procedures and at other times find it advantageous to proceed along entirely new lines of thought. If the manufacturer has adequate facilities for laboratory and clinical appraisal, he can usually obtain the desired information within a reasonable period. Frequently, however, such facilities are not immediately available and much effort must be spent in searching for appropriate channels for investigation. If a comprehensive outline had first been prepared and then closely followed, loss of time and expenditure of needless effort might have been avoided.

At the same time it is an advantage for physicians and allied scientists to know by what standards a new drug has been evaluated. When the physician is urged to use this agent, he should have available such evidence as will satisfy his questions concerning safety and efficacy.

The activities of the Council on Pharmacy and Chemistry of the American Medical Association in this field have recently been described.[2] Certain phases of the activities of the Food and Drug Administration which bear on this problem have also been published or are in press.[3]

The Council on Pharmacy and Chemistry has provided for almost 40 years a set of rules to guide manufacturers for the submission of articles for inclusion in "New and Nonofficial Remedies." At periodic intervals it has enlarged on these rules to provide criteria such as those found acceptable for the evaluation of skin disinfectants and contraceptives.[4] Usually the criteria have been concerned with one special agent or class of agents. The Federal Food, Drug, and Cosmetic Act provides that applications for new drugs shall contain "full reports of investigations which have been made to show whether or not such

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[1] The authors wish to express their appreciation of the helpful comments offered by Dr. Torald Sollmann, Dr. P. J. Hanzlik, and Dr. A. L. Tatum.

[2] Smith, Austin: "Membership, Activities, Method of Operation, Attainments of the Council," J.A.M.A. 124; 433 (Feb. 12), 1944.

[3] Woodard, Geoffrey, and Calvery, Herbert O.: "Acute and Chronic Toxicity," Industrial Medicine, January 1943. Calvery (see footnote 5). Van Winkle (see footnote 7). Draize, Woodard, and Calvery (see footnote 6).

[4] "Contraceptive Agents," report of Council on Pharmacy and Chemistry, J.A.M.A. 123: 1043 (Dec. 18), 1943; "Criteria for Evaluation of Skin Disinfectants," ibid., 121: 593 (Feb. 20), 1943.

drug is safe for use," and the Food and Drug Administration provides a form in which are set forth suggestions concerning the scope and character of these reports.

If the utmost of possible benefits with a minimum of possible dangers is to result when a new drug is introduced for experimental trial and later in commerce, it is necessary to develop methods of appraising the therapeutic usefulness and potential harmfulness of new drugs and to organize these methods into a logical system which, if followed, will give reasonable assurance that the new preparation will not be offered to the medical profession or to the public before the extent of its usefulness or the potentialities for harm are understood. The present paper outlines the principles which have been helpful in making such an appraisal of new drugs.

PRELIMINARY OBSERVATIONS

The preliminary experimental observations with a new agent give the clue to the possible field of usefulness. In dealing with chemotherapeutic agents, these preliminary observations consist usually of tests of the efficacy of the agent in combating or preventing some experimental infections. In the case of drugs that might be termed "symptomatic agents," the preliminary observations should include tests of the possible pharmacodynamic actions of the drug. These observations "set the sights," so to speak, and indicate the course to be pursued in subsequent and more detailed investigations.

LABORATORY OBSERVATIONS

Assuming that a new drug has shown promise in the preliminary tests, more extensive inquiry must now be made into the mechanisms of its action and its toxicity. In order for the clinician to use a drug intelligently he must know the manner in which its effects are brought about. The plan of procedure and the details of the tests to be employed should be formulated in accordance with the type of agent to be investigated, e.g., single chemical entity, complex extract, hormone, serum, or vaccine. The conditions in which the drug is thought to be useful and the observations made in the preliminary testing will also modify the plan of investigation and the details of the test procedures. Nevertheless, we feel that the following general types of study should prove to be applicable to most new drugs, keeping in mind that these are suggestive and not necessarily exhaustive:

(A) *Biochemistry.*—General properties of drug, including solubility, stability; studies of absorption, reabsorption, fate, distribution and excretion of the drug; quantitative data on these points where possible; mode of detoxification (excreted unchanged, oxidized, reduced, acetylated?); effect on enzymes, blood, and tissues; chemistry of body fluids and tissues; production of toxic products during course of metabolism.

(B) *Pharmacodynamics.*—Local: Tests of irritation on skin, eye, alimentary canal; intradermal irritation, sensitivity or anesthesia; tests of protoplasmic depression or toxicity, and reversibility of effects on cilia, nerve trunks, mucosa; hemolysis, antihemolysis, and blood pigment changes.

Systemic: Action on blood pressure, respiration, muscles, nervous system, cardiac functions, secretions, temperature, voluntary activity, organ perfusion, isolated tissues; effects of vasomotor agents, proteins, fats, metals, solvents and other agents on the actions of the drug; cumulative effects; development of tachyphylaxis; quantitative and qualitative differences in action in different species of animals.

(C) *Experimental Functional Pathology.*—Effects in experimentally induced pathologic states, e.g., smooth muscle spasm, hypodynamic hearts, fibrillations and arrhythmias, hypertension, respiratory depression, edema, shock, burns, anemias.

(D) *Chemotherapeutic.*—Effects in preventing specific experimental infections; effects in combating experimental infections or actions of toxins; antagonists of chemotherapeutic agents, e.g., pus, serum, tissue products; distribution in inflammatory states, e.g. meningitis, dermatitis; minimal effective dosage (ED50).

The data obtained from these studies will serve as a guide in the clinical application of the product and doubtless will also show evidence of undesirable or substantially harmful effects. If such effects are not observed, a careful search

must be made for them. This involves the very important study of the toxicology of the preparation. Woodard and Calvery,[5] Calvery [6] and Draize, Woodard and Calvery [6] have set forth in considerable detail the approach to the study of the acute and chronic toxicity of drugs and other chemical agents. Certain of the principles which they have formulated bear repetition here, and the original publications can be consulted for more detailed discussions.

Depending on the conditions for which the product may be used, on its biochemical and pharmacodynamic actions and on the methods of its use, adequate studies of its toxicity must be made. The following outline sets forth in general terms the scope that these studies should embrace:

(A) *Acute Toxicity.*—Dosage response curves in three or more species; objective symptoms; statistical calculations for comparative studies; simultaneous comparative determinations of other substances; variations in toxicity with method of administration.

(B) *Subacute Toxicity.*—Large daily doses to one or more species for six to twelve weeks; microscopic pathology.

(C) *Chronic Toxicity.*—Three or more species; at least one species for the life of the animal; several dosage levels graduated to produce from no effect up to pronounced lesions, and possibly shortening lifespan; microscopic pathology; effects on voluntary activity, e.g. running or other performance as evidence of more subtle functional changes.

(D) *Local Effects.*—Sensitization; skin irritation; mucous membrane irritation; photosensitization.

(E) *Special Studies.*—Reproduction; distribution and storage; effect of diet; effect of environment; kidney and liver function tests.

In selecting animals for investigation of new drugs it is important to use several distinct species, since it is well known that qualitative as well as quantitative differences exist between animal species in their reactions to drugs. Some species are wholly unsuited for demonstration of certain effects; e.g., methemoglobin is not readily produced in rodents and if the drug is suspected of causing this reaction rats, rabbits and guinea pigs are not suitable test animals. Rabbits are not usually satisfactory animals for blood pressure studies and often react atypically; e.g., histamine produces a rise of pressure instead of a fall. Emetics cannot be tested in rodents, since vomiting does not occur in these species. Many other examples could be cited, but these suffice to demonstrate the need for careful selection of suitable test animals.

Each investigator, including those concerned with clinical as well as laboratory investigations, should realize from the beginning where each specialty fits in the overall plan of study, e.g., chemistry, pharmacology, physiology, pathology. He should keep a careful record of all data and not be guided solely by impressions. The records should include actions not seemingly connected with the immediate project and dramatic response; for example, micturition, defecation, vomiting, pulse, respiration.

After completion of the experimental studies, a critical review of the accumulated data should be made. The purpose in this review is to reach a decision as to whether clinical trial of the drug is justified. It is difficult to set forth criteria on which this decision should be made, since the judgment of the investigators must always be an important factor. However, without any claim for completeness, the following points should be considered:

1. Has the drug definite and desirable pharmacodynamic or chemotherapeutic actions?
2. Are its actions constant and reproducible?
3. Are these actions observed in different species of animals?
4. Is the mechanism by which its actions are produced a desirable one, or are the actions the result of an ultimately undesirable reaction of the animal?
5. Are the effects obtained in animals in which experimentally produced pathologic or functional changes comparable to human diseases have been made?
6. What is the therapeutic index of the compound (ratio of effective dose to toxic dose: ED50/LD50)?

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[5] Calvery, Herbert O.: "Safeguarding Foods and Drugs in Wartime," American Scientist 32: 103–119, 1944.

[6] Draize, John H.; Woodard, Geoffrey: and Calvery, Herbert O.: "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membrances," to be published.

7. Are the undesirable side actions of sufficient importance and severity to militate against its clinical use?
8. Is there an adequate margin of safety in its use?

CLINICAL OBSERVATIONS

When sufficient information regarding the experimental actions of a new drug has been obtained to permit a logical decision to be reached that clinical trial is indicated, such studies may be commenced cautiously. The primary objectives to be reached in clinical investigation are twofold: (1) to determine the therapeutic efficacy and (2) to detect all signs of clinical intolerance or toxicity. The secondary, but nevertheless important, objectives are (1) to establish the effective dosage range for different age groups and conditions, (2) to determine the type and extent of collateral treatment necessary to obtain the maximum benefit from the drug, (3) to determine the best method of minimizing any undesirable side actions incident to the use of the drug and (4) to determine the contraindications and precautions to be observed in the use of the drug. Each clinical investigator should keep these objectives clearly in mind throughout his investigation in order that nothing may be overlooked.

Frequently the pharmaceutical manufacturer concerned with the development of a new product has neither the facilities nor the personnel to investigate the drug adequately. This is particularly true of clinical investigations. This work must be undertaken by others in cooperation with the manufacturer. The selection of the investigator is important, and it is a waste of time and money and may even be dangerous to place the investigation of the safety and efficacy of a new drug in the hands of incompetent or poorly trained individuals. Furthermore, it is important to select the investigator who has proper qualifications and training in the particular phase of the problem requiring study. A good pharmacologist is not necessarily a competent pathologist; a specialist in internal medicine may not be in a position to evaluate a product offered for nasal or sinus infections. Furthermore, not all specialists in clinical medicine are capable of conducting acceptable clinical investigations. The caliber and training of each investigator should be carefully considered before putting a problem in his hands. Clinical investigation of a new drug presents many very difficult problems. The heterogeneity of the persons under observation, the difficulty of securing adequate controls, the many extraneous and uncontrollable factors, the constant presence of subjective effects influenced by conscious or unconscious bias and many other unique conditions hamper the investigator in his efforts to secure the truth. Regardless of these, it is possible to suggest certain factors to be given consideration in conducting clinical investigations:

(*a*) *The Selection of Individuals To Be Observed.*—Cooperation from subject; absence of complicating factors; age; sex; emotional and psychic factors.

(*b*) *Diagnosis.*—Objective proof of diagnosis if possible, such as isolation and identification of infecting organism; X-ray evidence or other informative laboratory data; accurate description of lesion; differential diagnosis.

(*c*) *Control Observations.*—Preliminary control observations on the individuals; concurrent observations of untreated controls; alternation of treatment; alternation of treated and control subjects; posttreatment, control observations.

(*d*) *Observation During Treatment.*—Repeated physical and laboratory examinations; hematology; urinalysis; blood chemistry; x-ray; functional tests; precise objective measurements of improvements alleged to be produced by drug; determination of concentration of drug in blood, urine and other body fluids and the correlation of levels so observed with the dosage and the effect.

(*e*) *Number of Subjects.*—Sufficient number of treated individuals to minimize chance or other uncontrollable factors from influencing results; sufficient number of untreated control subjects. The results should be subjected to statistical analysis in order to determine their reliability.

(*f*) *Carefully Planned Administration of Drug.*—Controlled variation in dosage, frequency, method and duration of administration; effect of other drugs, and so on.

(*g*) *Criteria of Benefit.*—Establishment of criteria whereby the effects of the drug may be evaluated; objective tests; subjective observations; comparison with control treatments; comparison with natural course of disease.

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(*h*) *Separation of Subjective and Objective Observations.*—Use of "blind tests" (neither investigator nor subject knows which of several samples being administered is control or test product) or other methods to eliminate conscious or unconscious bias on part of observer and subject; careful separation of symptomatic reactions from objective findings; physchologic appraisal of subject.

(*i*) *Duration of Observation.*—Treatment to continue until any intrinsically undesirable or harmful manifestations have had time to develop as well as until sufficient time has elapsed to demonstrate beneficial effects; comparison of rapidity of cure or improvement with that of other methods of treatment.

(*j*) *More Than One Clinical Investigation.*—Several different investigators working independently; conclusions to be made independent of one another's results.

When the investigator is satisfied that he has a therapeutic agent which may be given satisfactorily by one route he should not by conjectural reasoning alone decide that it may be given safely and effectively by some other route. For example, if a product is safe and efficacious for oral use it may not be so when administered by rectum or by injection.

If it is decided to have several persons working on the clinical aspects of the problem, each one should provide a complete picture of the phase under investigation and not just a piecemeal study. Above all, it should be realized that summaries of case histories unless accompanied by the full report from which the summaries were derived are of little significance. A multiplicity of fragmentary case reports provide less information than a few complete and detailed reports of cases carefully and critically studied.

On completion of the clinical investigations it should be possible to provide definite answers to the questions implied in the statement of the objectives which were set forth at the beginning of this section. If these answers are not forthcoming from the data, more investigation is necessary. However, with the fulfilment of the objectives it is now necessary to decide whether the new drug has sufficient merit to be used in the alleviation of human suffering and in the treatment, prevention, or cure of disease. At the same time thought should be given to providing adequate warnings against use in certain pathologic conditions or against unsafe dosage or methods or duration of administration or application.

EVALUATION OF RESULTS

Two factors enter into the decision with regard to the merits of the drug: 1. Is it efficacious? 2. Is it dangerous? Neither of these factors can be separated one from the other and considered alone. This has been emphasized by Van Winkle[7] in discussing the evaluation of new drug applications submitted under the new drug provisions of the Federal Food, Drug, and Cosmetic Act. It has been emphasized that there is no arbitrary standard of safety; it is a relative matter in which the toxicity of the drug must be weighed against the therapeutic benefits which its use will bring about. Drugs with potentialities for harm and with only slight therapeutic effectiveness may be too dangerous for use, whereas another drug with the same potentialities for harm but with exceptional therapeutic usefulness may be relatively safe. Therefore, in evaluating the results of the clinical and experimental studies of a new drug, the following factors should be considered:

1. For what conditions is the drug to be offered?
2. How effective is it in these conditions?
3. Is it superior to other drugs and methods of treatment?
4. What is its inherent toxicity?
5. Does its toxicity outweigh the therapeutic advantages, keeping in mind the seriousness of the conditions for which it is being offered?
6. If there are other drugs equally or more effective in the same conditions, is the new drug less toxic or does it offer advantages in case of administration, duration of action and so on?
7. How extensive will the use of the drug be; are its applications limited?

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[7] Van Winkle, Walton, Jr.: "The Safety of New Drugs," Stanford Medical Bulletin 2: 103–107, 1944.

SUMMARY

A study of this outline for the therapeutic and toxicologic appraisal of new drugs may leave the impression that the task which has been set is far too complex and difficult, requires too much time and expenditure of energy and money, and can be circumvented by briefer and less thorough investigations. While this may be true in a few isolated instances, it is not true in the majority of cases of really new drugs. Recent history contains too many instances of disastrous results that have followed incomplete or inadequate investigation of new drugs. This outline is an objective toward which investigations of new agents should be directed. It need not apply in full to all cases, but the reasons for omitting any part should be that the omitted parts of the program are not necessary and not merely that they are troublesome. It should also be borne in mind that new methods and new criteria may be developed and these should, of course, be applied when indicated.

Finally it is necessary to exercise sound judgment in deciding whether a product deserves recognition, and the only basis on which such a judgment can be made is by a careful appraisal of the data obtained through a systematic study. Investigations of new therapeutic agents are perhaps the most exacting of all scientific investigations since human health, and even life, may depend on the thoroughness of these investigations. Furthermore, failure to interpret correctly the results of the tests conducted and criteria for their evaluation may be disastrous.

EXHIBIT 301

[From Washington Post, Apr. 19, 1960]

DRUGMAKERS PLAN STUDY OF COST IMPACT

The Nation's organized drugmakers plan a full-scale study of the impact of drug costs on the American public, it was announced here last night.

The fact-finding is designed to consolidate information never before assembled by any source, public or private, said Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association.

Dr. Smith said the 2-year-old association will make the findings available for public examination, in line with PMA's public service policies.

Specifically, the study is aimed at determining the extent of use of prescription drugs by the general public, the ways in which drugs are provided in medical care programs, the availability or unavailability of drugs for the sick, and the true role of prescription drugs in medical care needs and costs.

The American Medical Association recently announced the start of a full-scale study of medical care costs. The PMA study, it was explained, will limit itself to prescription drug costs to the general public to the exclusion of other medical costs.

Dr. Smith said representatives of consumer groups and health workers will be asked to serve with members of a special industry group, whose membership will be announced shortly. The unified fact-finding, he said, will bring together the drug makers, members of the health team, public authorities and the patients themselves.

Both the AMA and PMA studies were instituted after widespread criticism of the high cost of drugs and medical care. Witnesses at the current Senate antitrust hearings on the subject, conducted by Senator Estes Kefauver, Democrat, of Tennessee, have testified to excessive drug costs and high profit taking by the drug makers, distributors, and retailers.

MAY 18, 1960.

Mr. EDWARD J. DOHERTY,
HILL & KNOWLTON, INC.,
New York, N.Y.

DEAR MR. DOHERTY: During Dr. Smith's testimony on April 20 before the Kefauver subcommittee, there arose (transcript, p. 4204) a question as to the source of a suggested press release on the subject of pharmaceutical research which appeared in West Coast Druggist magazine for January 1960. Senator Kefauver asked Dr. Smith specifically whether your firm had anything to do with this.

Will you please check to see whether or not Hill & Knowlton did have anything to do with the matter and advise me in order that we may respond to the Senator's request?

Sincerely,

WM. KLOEPFER, JR.

HILL & KNOWLTON, INC.,
New York, N.Y., May 24, 1960.

MR. WILLIAM KLOEPFER, JR.,
Director of Information, Pharmaceutical Manufacturers Association,
Washington, D.C.

DEAR MR. KLOEPFER: This refers to your letter of May 18 in which you asked whether Hill & Knowlton had anything to do with an article in West Coast Druggist magazine, referred to on page 4204 of the transcript of the drug inquiry.

A check of our files indicates that Hill & Knowlton has prepared no fill-in release for use within the drug industry or for publication.

Hill & Knowlton has to date had no contact with West Coast Druggist magazine so far as we can determine.

It follows then that we had nothing to do with the article which was partially quoted by Senator Kefauver during Dr. Smith's appearance before the subcommittee on April 20, 1960.

Very truly yours,

EDWARD J. DOHERTY.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 20, 1960.

Hon. ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust & Monopoly,
Senate Office Building, Washington, D.C.

DEAR SENATOR KEFAUVER: Pursuant to Dr. Austin Smith's request during the April 20 hearings of the Senate Subcommittee on Antitrust and Monopoly, which you kindly granted (transcript of hearings, vol. 21. p. 4251) I am enclosing a table showing the 1958 total net sales figures of 15 firms for ethical pharmaceutical drugs produced exclusively for human use. These figures are supplied along with total net sales of pharmaceutical products and preparations for both human and veterinary use, as reported to the subcommittee by 22 companies on the subcomittee's form I, line 1, column 3.

We have received permission from each of the firm to submit their figures to you and your staff on individual but confidential basis, and with the understanding that they will not be made a part of the hearings record.

In addition to these firms, American Cyanamid Co., the Norwich Pharmacal Co., Vick Chemical Co., and Chas. Pfizer & Co., Inc., report a total net sales of human ethical pharmaceuticals in 1958 of $377,608,000. The total net sales of these four firms of human and veterinary drugs, as reported in form I, is $554,270,000.

The grand total of net sales for the 19 firms is $1,597,563,000 in human ethical pharmaceuticals, and $1,938,194,000 in human and veterinary ethical products.

Three firms reporting total net sales in 1958 on subcommittee form I, American Home Products Corp., Hoffmann-La Roche, Inc., and Smith, Kline & French Laboratories have not responded to our questionnaire.

Sincerely,

WM. KLOEPFER, Jr.

Company	Total net sales, 1958 (reported to Senate subcommittee on form I)	Total human ethical pharmaceutical sales, 1958
Abbott Laboratories	$116,598,000	$112,169,000
Bristol Laboratories, Inc	19,183,000	19,183,000
Ciba Pharmaceutical Products, Inc	37,854,000	37,854,000
Carter Products	30,771,000	23,330,000
Eli Lilly & Co	176,728,000	166,130,000
Mead Johnson & Co	30,785,000	30,785,000
Merck & Co., Inc	206,636,000	176,387,000
Olin Mathieson Chemical Corp. (E. R. Squibb & Sons)	109,185,000	98,801,000
Parke, Davis & Co	172,583,000	172,387,000
Schering Corp	75,180,000	68,882,000
G. D. Searle & Co	32,667,000	32,667,000
Sterling Drug Co	163,050,000	70,818,000
U.S. Vitamin & Pharmaceutical Co	14,493,000	14,175,000
The Upjohn Co	146,136,000	143,713,000
Warner-Lambert Pharmaceutical Co	52,075,000	52,075,000
Total	1,383,924,000	1,219,356,000

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 18, 1960.

Hon. ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust and Monopoly,
Senate Office Building, Washington, D.C.

DEAR SENATOR KEFAUVER: Pursuant to the remarks at page 4338 of the transcript of the April 20 hearings of your subcommittee in its investigation of the drug industry, Dr. Austin Smith asked a representative of the American Medical Association if information was available on the reasons for the association abandoning its so-called seal or acceptance program. As he advised you during the headings, the AMA representative suggested that such questions might be more properly addressed directly to the American Medical Association.

However, there was a statement that appeared in the February 19, 1955, issue of the Journal of the American Medical Association in an editorial entitled "AMA Councils Expand Their Programs" which may be of interest. This sentence reads: "The so-called acceptance program has been useful and helpful, but the need for it has become much less as laws have been enacted and as manufacturers have assumed more and more their share of responsibility in marketing worthwhile products."

Sincerely,

WM. KLOEPFER, Jr.

AUTHORITIES WHO ACCOMPANIED DR. AUSTIN SMITH

(NOTE.—These papers identify eight authorities in economics, medicine, and pharmacy who are accompanying Dr. Austin Smith, president of PMA, in his appearance before the Senate Committee on Antitrust and Monopoly Legislation.)

DR. WILLIAM S. APPLE, SECRETARY AND GENERAL MANAGER, AMERICAN PHARMACEUTICAL ASSOCIATION

Born in Spokane, Wash., in 1918.

Attended Wayne State University and the University of Wisconsin. Received a bachelor of science degree in pharmacy, a masters degree in business administration, and a doctor of philosophy degree from the University of Wisconsin. Was awarded fellowships by the American Foundation for Pharmaceutical Education.

Served in U.S. Army, 1941–46, advancing from private to major. Is currently lieutenant colonel in the U.S. Army Reserves.

In 1960 delegate to U.S. Pharmacopeia Convention.

Former chairman, Department of Pharmacy Administration, University of Wisconsin.

GROVER C. BOWLES, DIRECTOR OF PHARMACY SERVICE, BAPTIST MEMORIAL HOSPITAL, MEMPHIS, TENN.

Born in Piedmont, Mo., February 15, 1920.

He received his B.S. in pharmacy at the University of Tennessee and is now a member of the faculty. He is a registered pharmacist in Tennessee and New York. He is a contributing editor of the American Journal of Hospital Pharmacy and the Modern Hospital. Mr. Bowles is a member of the Council of A. Ph. A. He is a member of the NF advisory committee, committee on status of pharmacists in Government service, committee on social and economic relations, and committee on publications. He is a member of the ASHP executive committee and chairman of their publications committee. He is a past president of ASHP. He is a member of NARD, AAAS, AHA, Phi Delta Chi, FIP, and Tennessee Pharmaceutical Association.

ARTHUR CHRISTIAN DE GRAFF, M.D., PROFESSOR OF THERAPEUTICS, NEW YORK UNIVERSITY, AND CHAIRMAN, SUBCOMMITTEE ON SCOPE, U.S. PHARMACOPEIA

Born in Paterson, N.J., December 3, 1899.

B.S., New York University, 1920, M.D., 1921. Intern and house physician Bellevue Hospital, New York City 1921–23; instructor in medicine, New York University Medical College 1923–24; Crile research fellow in physiology, Western Reserve University, Cleveland, 1924–25; instructor in physiology, New York University Medical College, 1925–27; Samuel A. Brown professor of therapeutics since 1932; practiced, New York City since 1927, specialist in heart disease; visiting physician third medical division, Bellevue Hospital, snce 1936; consulting cardiologist, Meadowbrook Hospital (Hempstead, Long Island), St. Agnes Hospital (White Plains, N.Y.), Hackensack (N.J.) Hospital; consulting cardiologist, New York Infirmary, Nassau Hospital, Mineola, Long Island; chairman, medical board, Irvington House; consultant in cardiology, Mount Vernon (N.Y.) Hospital, Kingsbridge Hospital, VA; consultant on internal medicine staff, Ossining (N.Y.) Hospital; attending physician on medical service, University Hospital, New York University-Bellevue Medical Center.

Member revision committee, U.S. Pharmacopeia; fellow, American College of Physicians; member, American Society Research in Psychosomatic Problems, American Society Pharmacology and Experimental Therapeutics, American Medical Association, Society for Experimental Biology and Medicine, American Federation Clinical Research, American Physiology Society, American Society for Clinical Investigation, New York Academy of Medicine, New York Heart Association (member board of directors), American Therapeutic Society, New York County, Westchester County Medical Societies, American Heart Association, Biometric Society, Arthritis and Rheumatism Foundation, American Council on Rheumatic Fever and Congenital Heart Disease, Harvey Society, Society Alumni Bellevue Hospital, Sigma Xi Omega Alpha.

GEORGE FAIRLESS LULL, M.D., ACTING SECRETARY, ILLINOIS STATE MEDICAL SOCIETY

Born in Scranton, Penna, March 10, 1887.

M.D., Jefferson Medical College, 1909, LL.D., 1949; M.P.H., Harvard, 1921; Dr. P.H., University of Pennsylvania, 1922; LL.D., Jefferson Medical College, 1949, Doctor of Science (honorary), Woman's Medical College, Pennsylvania, 1953; intern, Jefferson Hospital, 1909–10, demonstrator morbid anatomy, 1910–12; commanding officer, Medical Corps, U.S.A., 1912, and advanced through grades to major general, 1943; secretary and general manager, American Medical Association, 1946–58, secretary and assistant to the president, 1958–59.

Decorated, Purple Heart, Distinguished Service Medal (United States); Legion of Honor (France), Order Carlos Finlay (Cuba).

Fellow American College of Chest Physicians (honorary), American College of Surgeons, American College of Physicians; International College of Surgeons (honorary); member American Public Health Association, Association Military Surgeons, Alpha Omega Alpha, Phi Rho Sigma.

DR. RUFUS BENJAMIN ROBINS, SURGEON, CAMDEN, ARK., AND MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Born in Ozan, Ark., October 27, 1899.

S.B., Hendrix College, Conway, Ark., 1921; M.S., University of Chicago, 1923, M.D., 1925. Surgeon, Camden (Ark.) Hospital, since 1926; owner, Robins Clinic, Camden, Ark., since 1937; Alderman, city of Camden, 1940–52; professor medical economics, University of Arkansas; chief of staff, Ouachita County Hospital, Camden, Ark. Served as private Infantry, U.S. Army, World War I. Democratic national committeeman for Arkansas, 1944–52. Fellow, International College of Surgeons, American College of Surgeons, Southwestern Surgical Congress (founder); Associate fellow, American Therapeutic Society, member, American Medical Association (vice president), Arkansas Medical Society (past president), Tri-State Medical Society (past president), Mid-South Medical Assembly (past vice president), American Academy of General Practice (past president). Mason (32d degree Shriner). Past district governor for Arkansas Lions International, past member executive committee, board of governors; past president Camden Lions Club.

GEORGE L. SCHARRINGHAUSEN, JR., PHARMACIST, PARK RIDGE, ILL.

Born in Chicago, Ill., November 21, 1905. He graduated from the University of Illinois College of Pharmacy in 1928 and did postgraduate work in accounting and advertising at Northwestern University. Since graduation he has been actively associated with the Scharringhausen Pharmacy of Park Ridge which was started by his father in 1924. He has a son and daughter who are also pharmacists. He joined the A. Ph. A. in 1950 and was chairman of the section on pharmaceutical economics in 1957.

Mr. Scharringhausen is president-elect of the Illinois Pharmaceutical Association and holds membership in the Chicago Retail Druggists' Association and NARD. He is also a member of Kappa Psi and Kiwanis and is the vice president of the Park Ridge Federal Savings & Loan Association.

He filled his 1 millionth prescription in October 1959. Mr. Scharringhausen employs nine pharmacists in his pharmacy in Park Ridge.

FREDERICK L. THOMSEN, PH. D., ECONOMIC CONSULTANT

Born: Newport News, Va., August 7, 1898.

Second lieutenant of Infantry, U.S. Army, 1918–19.

B. S., University of Maryland, 1917; M. S., 1919 and Ph. D., 1925, University of Wisconsin.

Professor of marketing, University of Missouri, 1925–36.

Lecturer in economics, Graduate School of the Department of Agriculture and American University (serving all Federal Government departments), Washington, D.C., 1937–47.

Associate Head, Division of Statistical Research, BAE, USDA, 1936–42.

Head, Division of Marketing and Transportation Research, BAE, USDA, 1942–46.

Director, Marketing Research Branch, Production and Marketing Administration. USDA, 1947–49.

Executive vice president, Commodity Marketing Corp., New York City, 1950–52.

Consulting economist, St. Petersburg, Fla., 1953–.

Author:

"Agricultural Marketing," McGraw-Hill Book Co., 1951 (See chap. 7 for discussion related to imperfect competition and monopoly.)

"Agricultural Prices," McGraw-Hill Book Co., 1952. (See pp. 97–107 for discussion of pricing under imperfect competition.)

(These two textbooks used in over 50 colleges and universities in the United States, and widely used in other countries.)

Scores of articles and resarch reports in professional journals, university bulletins, Federal Government publications, and trade magazines.

Residence: St. Petersburg, Fla.

DR. LINWOOD FRANKLIN TICE, DEAN, PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE, PHILADELPHIA, PA.

Pharmaceutical chemistry. Salem, N.J., Feb. 17, 09; PhG, Phila. Col. Pharmacy, 29, B.Sc, 33, M.Sc, 36, Iodine Ed. Bur fellow, 29–30, Warner fellow, 31–35, Edible Gelatin Mfrs. Research Soc. Am. fellow, 35–38, Sharp & Dohme fellow, 38–40. D.Sc, St. Louis Col. Pharmacy & Allied Scis, 54. Prof. pharmacy, Baylor, 30–31; asst. prof, Phila. Col. Pharmacy, 38–40; Prof, 40– ; Asst. Dean 41– ; Consultant, Gelatin Research Soc. Am. 38– ; lectr, Wagner Inst, 46– ; Ed, "American Jour, Pharmacy," 40– ; tech. ed, Pharmacy Int, 46– ; mem. revision cmt, U.S. Pharmacopeia. A. A.; Chem. Soc; fel. Inst. Chem; Pharmaceut. Assn; N.Y., Acad. Pharmaceuticals; colloids; proteins.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 23, 1960.

Senator ESTES KEFAUVER,
Chairman, Subcommittee on Antitrust and Monopoly,
U.S. Senate, Washington, D.C.

DEAR SENATOR KEFAUVER: Attached is a written description of the charts which I displayed in my testimony before your subcommittee today, describing the manufacturing and control prices of aspirin and of a tranquilizer.

This is the material requested for the record by Senator Hruska.

Sincerely,

AUSTIN SMITH, M.D.

The chart entitled "Typical Manufacturing Process—Tranquilizer Product Flow Diagram—Manufacturing Formula" is approximately 14 inches wide and over 9 feet long.

It lists, in typewriter lettering, mostly single spaced, steps in the process, a brief description of each, the number of employees involved in each, the man-hours required for each, and the yield. The last several lines are a summary repetition of a major part of the document.

The chart on aspirin is about 11 inches wide and 7 feet long. It gives much the same kind of information as the tranquilizer chart with the steps diagramed in sequence and in some cases illustrated with small photographs. It also contains a very brief summary at the bottom and is slightly larger type face than the typewriter size on the tranquilizer chart.

AUSTIN SMITH, M.D.,
President, Pharmaceutical Manufacturing Association.

PROFIT ON PERCENT OF SALES

46 MANUFACTURING INDUSTRIES, 1958

[From News Front magazine, November 1959]

	Percent
Iron and steel	6.0
Motor vehicles and motor vehicle equipment	4.0
Aircraft and parts	2.3
Ships and boat building and repairing	3.5
Railroad equipment	3.7
Transmission and distribution equipment	4.9
Household appliances	4.6
Radio and television sets	2.7
Communications equipment	3.1
Instruments	6.7
Tires and innertubes	4.1
Miscellaneous rubber and plastic products	3.6
Footwear and leather tanning and finishing	4.3
Drugs	10.6
Chemicals, organic and inorganic	8.3
Paints and varnishes	6.5
Agricultural chemicals	5.8
Miscellaneous chemical products	8.6
Meat products	5.7
Dairy products	2.7
Canning and preserving	3.5
Grain, mill products	3.9
Bakery products	3.1
Fabricated metal products	3.7
Machinery	5.5
Machinery, farm, construction, and mining	4.5
Metalwork, machinery and equipment	3.5
Special industrial machinery	3.4
General industrial machinery	5.9
Office, accounting, and computing	5.7
Service industry machines	2.3
Mineral products	7.6
Cement	16.2
Glass and glass products	7.4
Clay products	7.8
Furniture and fixtures	5.1
Lumber and wood products	6.3
Sugar	3.5
Confectionery and related products	7.5
Nonalcoholic and carbonated waters	7.9
Alcoholic and malt beverages	3.6
Cigarettes, cigars, etc	5.6
Paper, pulp, and allied products	6.3
Textile and knitting mill products	2.5
Floor coverings	5.3
Miscellaneous manufacturing	4.7

TITLE 42.—THE PUBLIC HEALTH AND WELFARE

§ 262. Regulation of biological products.

(a) Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales.

No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any

virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

(b) Falsely labeling or marking package or container; altering label or mark.

No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid so as to falsify such label or mark.

(c) Inspection of establishment for propagation and preparation.

Any officer, agent, or employee of the Department of Health, Education, and Welfare, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.

(d) Regulations governing licenses.

Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

(e) Interference with officers.

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses.

Any person who shall violate, or aid or abet in violating any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws.

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act. (July 1, 1944, ch. 373, title III, § 351, 58 Stat. 702; 1953 Reorg. Plan. No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Sept. 2, 1958, Pub. L. 85-881, § 2, 72 Stat. 1704.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text of subsec. (g), is classified to chapter 9 of Title 21, Food and Drugs.

AMENDMENTS

1958—Subsec. (d) amended by Pub. L. 85–881, which eliminated words "made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of thhe Navy, and approved by the Secretary" following "regulations" in first sentence.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

CROSS REFERENCES

Regulation of biological products for use in treatment of domestic animals, see sections 151–158 of Title 21, Food and Drugs.

WASHINGTON, D.C., *February 24, 1960.*

Hon. ESTES KEFAUVER,
U.S. Senate, Washington, D.C.

DEAR SENATOR KEFAUVER: I was pleased to appear with Dr. Austin Smith at the drug hearings and at your suggestion I want to make the following coments:

(1) You would no doubt want to know my feeling about prescribing drugs by generic name.

It is rather impractical and awkward for a physician to do this in most instances because of the following reasons: Many firms, especially small firms, peddle cheap generic products. I want my patients to have top-quality drugs and I want to know what firm is going to supply the drug for my patient. For that reason I like to use the trade name. It is simpler to write such a prescription and I can be assured that no substitution will be made by the druggist—this assures me that the patient will get top quality.

The same generic drugs are not always equivalent. The U.S.P. label gives no assurance of potency.

(2) My feeling toward advertising and detail men is that they are very helpful to the doctors and in turn to the patients of America and their health. Physicians are intelligent and discriminating. The above two media of communications are educational reminders of the values of various products. A good detail man saves the physician much educational effort by encouraging him to learn more about specific drugs. He brings initial information to the physician sooner than it appears usually in scientific articles and allows the physician an opportunity for questions.

Another point I might stress is that the physician may obtain an ample supply of expensive drugs for his indigent patients. Pharmaceutical companies are very gracious about this.

(3) The third point I want to stress with you is that 85 percent of our prescriptions can be filled at the drugstore for less than $5. In fact, over 60 percent of all prescriptions were $3 and under.

Senator, it was a pleasure to visit with you again as our personal friendship has existed over a period of many years.

Please file this personal letter to you in the record of the hearings.

With warm personal regards, I am,

Sincerely,

BOB ROBINS, M.D.

P.S.—I appeared at these hearings strictly as a private practicing physician and not as a representative of any organization.